

# Animal health law

## Rules on transmissible animal diseases

### SUMMARY

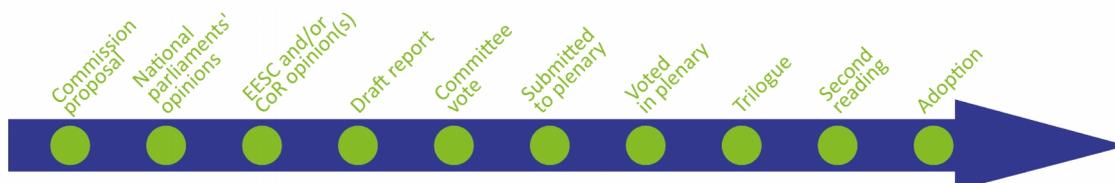
Transmissible animal diseases can have a significant impact on animal and public health and on the economy. Current EU legislation in the field developed over decades and consists of a large number of acts. In an evaluation initiated by the Commission, the legislation was assessed as generally well-functioning and effective, but also as complex and lacking an overarching strategy. The rules, often adopted in response to crises, focus on combating diseases rather than on prevention.

The Commission has proposed to create a single regulatory framework for rules related to the control of transmissible animal diseases. Most current provisions would be adapted, aligned and made more coherent. The proposed regulation would introduce prioritisation and categorisation of diseases, clarify responsibilities and place stronger focus on disease prevention. Most of the existing acts would be repealed.

After trilogues in view of an early second reading agreement, Parliament approved the agreed text during its plenary session on 8 March 2016.

### Proposal for a regulation of the European Parliament and of the Council on Animal Health

<i>Committee responsible:</i>	Agriculture and Rural Development (AGRI)	COM(2013) 260 of 06.05.2013
<i>Rapporteur:</i>	Jasenko Selimovic, (ALDE, Sweden) Marit Paulsen (ALDE, Sweden) (until 29 September 2015)	<i>procedure ref.:</i> 2013/0136 (COD)
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<p><b>In this briefing:</b></p> <ul style="list-style-type: none"> <li>• Introduction</li> <li>• Context</li> <li>• Existing situation</li> <li>• The changes the proposal would bring</li> <li>• Preparation of the proposal</li> <li>• Parliament's starting position</li> </ul>	<ul style="list-style-type: none"> <li>• Stakeholders' views</li> <li>• Advisory committees</li> <li>• National parliaments</li> <li>• Parliamentary analysis</li> <li>• Legislative process</li> <li>• References</li> </ul>
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## Introduction

The [proposal](#) for a regulation on animal health adopted by the Commission on 6 May 2013 is the result of a long process to review EU policy in this area.

In 2004 the Commission launched an external evaluation of the Community Animal Health Policy (CAHP) over the previous decade (1995–2004). In the [report](#) on this evaluation, published in July 2006, the policy was assessed to function well. It was noted, however, that it was a set of multiple inter-related policy actions rather than a coherent framework, and recommended that a single strategy for animal health be developed. On the basis of this evaluation, in September 2007 the Commission published a Communication presenting a new [Animal Health Strategy](#) for 2007–2013 with the motto 'Prevention is better than cure'. Strategic goals for animal health were set out for the first time. One of the objectives was also the adoption of a 'single regulatory framework for animal health'. The 2008 [Action Plan](#) for the implementation of the Strategy set an indicative timeline for the preparation of a legislative proposal on an Animal Health Law.

This proposal is also part of a [package](#) 'Smarter rules for safer food' brought forward by the Commission with the aim to review, simplify and modernise the existing legislation covering the whole agri-food chain. This package includes proposals for regulations on animal health, plant health, plant reproductive material and official controls, as well as a common financial framework: Regulation (EU) 652/2014<sup>1</sup> adopted on 15 May 2014.

## Context

### Transmissible animal diseases

Animals may suffer from various diseases, a number of which are transmissible to other animals, either through direct contact or indirectly (for example via insects). Transmissible diseases may have broad and significant impacts, not only on the health of animals, but also in economic terms. They can lead to important losses: in animal production (resulting from the death of animals or from their reduced productivity), in trade (disease-free countries can restrict imports from the countries affected), as well as losses due to the costs of the eradication measures for the public and private sector. For instance, the costs of the [foot-and-mouth disease outbreak](#) in the UK in 2001 have been estimated at over £8 billion. More than 6 million animals (sheep, cattle and pigs) were slaughtered.

Some animal diseases (called zoonoses) are also transmissible to humans and therefore can pose a risk to public health (for example, [tuberculosis](#), [brucellosis](#) and [rabies](#)).

### Measures to control transmissible animal diseases

Measures undertaken to control an animal disease depend primarily on the potential impact of the disease (on animal and public health and on the economy) and on the risk of it spreading (paths of transmission, level of contagiousness). For example, foot-and-mouth disease ([FMD](#)), which affects cloven-hoofed animals (primarily cattle, pigs and sheep), is usually non-fatal, nor does it pose a risk to humans. It has, however, exceptional economic importance. It is one of the most contagious animal diseases: it can be transmitted by contact, via the breath of infected animals and even by wind. Therefore it can spread widely and rapidly, reaching large animal populations; an outbreak can have disastrous economic consequences (as illustrated above). Control and eradication measures (currently laid down in [Directive 2003/85/EC](#)) include slaughter and disposal of infected and at-risk animals, establishing of protection and surveillance zones around the outbreak, restriction of movement for susceptible animals and their products. On the other hand, [bluetongue](#), a disease affecting ruminants, is transmitted by specific species of insect. It does not spread through contact between animals in the absence of these insects and is not transmissible to humans. Control and eradication is carried out through use of insecticides in animal housing and in areas where the insects are present, applying insect repellents to animals, restriction of movement of susceptible animals from affected areas to non-infected regions where the insects are present, as well as the use of vaccines.

The design of any measures to tackle transmissible diseases should be based on scientific advice. On EU level such advice is provided by the [European Food Safety Authority](#).

### Prevention

The Community Animal Health Policy evaluation highlighted the need to focus more on preventing disease outbreaks before they occur. Important tools in prevention are biosecurity and vaccination. **Biosecurity** refers to precautionary measures taken to reduce the risk of introduction, development and the spread of diseases. They include, for instance, separation of new animals from existing stock, isolation of sick animals, regulation of the movement of people, animals, and equipment, correct use of feed, as well as procedures for cleaning and disinfecting facilities. Particular responsibility for this kind of preventive measures lies with the animal owners, operators, and others working with animals. **Vaccination** can be a good tool to prevent outbreaks of animal diseases and also reduce their impact when they occur. However, vaccination can also cause economic problems. A vaccine protects against occurrence of a disease, but not fully from infection, so an animal can still be a carrier of the infectious agent. Disease-free countries can restrict imports against the fear of introducing the disease through vaccinated animals or products from such animals. Under the current EU legislation, vaccination is prohibited for major transmissible animal diseases (such as foot-and-mouth disease or classical swine fever). The prevailing approach is culling (slaughter and destruction) of animals in case of an outbreak. However, this non-vaccination policy has been debated intensely in the EU in recent years, after several outbreaks which resulted in the slaughter of many animals, and raised economic and ethical concerns. During the work on the Animal Health Strategy, stakeholders and policy-makers recognised the need to review the approach to vaccination in line with the principle 'vaccination is better than unnecessary culling'.

### Notification and information

Transmissible animal diseases do not stop at borders. Thus, there is a need to coordinate control and surveillance actions beyond national level. The first step is notification and information. In case of the outbreak of a disease, the state affected should report it, and the information should be rapidly forwarded to others. At EU level the notification of diseases is currently regulated by [Directive 82/894/EC](#) which also lists notifiable diseases. Member States are obliged to report outbreaks through the Animal Disease Notification System ([ADNS](#)), which registers and documents the situation regarding important infectious animal diseases. On the global level, the World Organisation for Animal Health ([OIE](#)) has dealt with animal health issues since 1924, and establishes and updates a [list](#) of notifiable diseases. Member states report through the World Animal Health Information System ([WAHIS](#)); the information is then disseminated to other countries. The OIE also runs a World Animal Health Information Database ([WAHID](#)) where the data from WAHIS are accessible to the public. All EU Member States are members of the OIE, the EU has observer status.

### Movement of and trade in animals

The risks of spreading a disease include those related to moving animals between different areas – within one country or cross-border. Therefore movements of live animals are not free, but are subject to certain requirements concerning animal health. For movements between Member States and for entry into the EU from third countries the requirements are set at EU level. Before animals can be moved between Member States for commercial purposes, they must undergo veterinary examination and obtain a certificate. The movement has to be notified in [TRACES](#) (the EU system for tracing animal and animal product movements) and in national databases. This traceability of animals is of crucial importance in case of a disease outbreak.

In the context of risk analysis and biosecurity, the OIE promotes the concept of **compartmentalisation**. Compartments are subpopulations of animals delimited according to their health status and considered homogenous with respect to this status. The same level of risk is assumed and the same type of disease control and biosecurity measures can be applied. This concept is used in international trade. In EU legislation it is currently only introduced for diseases in [aquatic animals](#) and for [avian influenza](#).

### Existing situation

The existing EU legislation on matters related to animal health consists of some 50 basic acts (directives and regulations which lay down general principles, applying, among others, to animal identification, disease surveillance and control, notification of diseases, intra-EU and international trade, and veterinary controls); and around 400 secondary acts: some 200 that lay down implementing rules (for example on registration or veterinary certification) and a further 200 special acts with specific provisions (such as rules on protection for particular diseases). These rules date largely from the 1980s and 1990s, some even from the 1960s. They were created piecemeal, often in response to crises related to disease outbreaks.

During the evaluation of the Common Animal Health Policy (CAHP) the current system was considered both effective and successful in reducing the occurrence of animal diseases and improving the response to crises. However, some areas for improvement were also identified, and are outlined below.

**Complex legislation, many legal acts, no single horizontal law**

With the **large number of legal acts**, accumulated over decades, it is not uncommon that rules related to a particular matter (such as obligations for animal keepers or animal health requirements for imports) are scattered throughout the legislation, which makes them difficult to find and to apply. Obligations, roles, tasks and duties of actors (animal keepers, owners, veterinarians, competent authorities etc.) are not always distinctly defined and divided, and **responsibilities not always clear**. There is also a lack of clarity regarding the **definition of veterinary services** and their tasks. Different acts<sup>2</sup> give different definitions of 'competent authority', 'official veterinarian', or 'approved veterinarian'. This creates a risk of divergent interpretations in Member States and leads to incoherence in the attribution of duties. Another issue is that certain **rules apply equally to commercial and to non-commercial activities** (for example rules on keeping animals or intra-EU movements), not always proportionately to the risk.

**Lack of an overall strategy**

The current legislation consists of many measures and actions, but lacks a comprehensive approach and strategy to prevent and control animal diseases, with consistent principles and objectives. There is **no categorisation and prioritisation** of animal diseases with regard to the policy measures applied to them (which are sometimes undertaken on political or crisis-driven grounds). Categorisation of diseases according to the risk they pose would help in allocating resources where they are most needed and most effective. As regards **coordination of disease surveillance**, there are different actors and systems (for example EU harmonised or not harmonised; compulsory or voluntary; applied to farmed animals or to wildlife), and the rules are fragmented and unclear. The current **harmonisation of EU legislation with international standards** is not sufficient; for better consistency with international trade rules, EU legislation should reflect the OIE standards, to which all Member States adhere. Also, the existing rules are in many cases too rigid and difficult to rapidly **adapt to new developments**. There are no appropriate and flexible tools for responding to **emerging and exotic diseases**. Knowledge about emerging diseases (new diseases that did not exist before or diseases that are new to a territory), as well as exotic diseases (diseases not commonly present in a territory), is generally lower than for known diseases. This means lower preparedness in case of an outbreak. General EU measures for the control of certain animal diseases are laid down in [Directive 92/119/EEC](#), but these measures refer to a limited list of emerging or exotic diseases.

**Insufficient focus on disease prevention**

The current legislation is excessively focused on dealing with diseases when outbreaks occur, according to the evaluation, rather than preventing them from occurring in the first place, which could save valuable resources. One of the obstacles is the **suboptimal use of surveillance mechanisms** to prevent disease outbreaks. Another is **insufficient biosecurity measures on farms**. Farmers are often the best placed persons to prevent animal diseases. However, there are no comprehensive rules on farm biosecurity measures and only few mechanisms at EU level that would promote such measures by animal keepers. Existing schemes are mainly voluntary or industry-led and tend to have a lower uptake than regulatory mechanisms. There are also no provisions obliging people dealing with animals on farms to have a level of **knowledge of animal health**. They often may be not sufficiently aware of the potential impacts of animal diseases and of the biosecurity measures they could implement. A further issue is the **suboptimal level of use of vaccination** for major animal diseases.

### Suboptimal rules for intra-EU trade

The current EU rules on animal health with regard to commercial movements of live terrestrial animals between Member States are not optimal, the evaluation found. Often the same information has to be entered several times in different systems: TRACES, the EU disease notification system ADNS, and the OIE international WAHIS system. This is an unnecessary and burdensome **duplication of procedures**. Moreover, the requirements do not always proportionately reflect the actual risk (for example in the case of cross-border movements between neighbouring countries with the same health status). A solution to balance the level of measures with the level of the health risk could be compartmentalisation. However, the **concept of compartmentalisation is not widely applied in EU law**. It could be extended and used for the purposes of international and intra-EU trade.

### The changes the proposal would bring

The new regulation aims to address the problems identified before. As set out in the Animal Health Strategy, it would establish a **single regulatory framework** for animal health which would integrate, streamline and simplify the existing legislation. Intended as a framework, the regulation itself would only lay down general principles and basic rules. Detailed provisions would be established later by delegated or implementing acts (taking over the elements of existing legislation which currently function well). This should allow the flexibility to react to new situations. The new law would also place **stronger focus on prevention** and be better aligned to international standards, particularly the OIE.

The **scope** of the regulation would cover transmissible animal diseases and all categories of animals: terrestrial and aquatic, kept animals of all types (farm and pet animals, animals kept for research purposes, for leisure etc.) and also to some extent wild animals (where there is a risk of transmitting a disease to other animals or to humans).

The proposal introduces (Part I) the **listing, categorisation and prioritisation of diseases**. Those most likely to have serious impact and requiring intervention at EU level are to be listed and grouped in five categories according to the risk they pose; different measures would be applied to different categories. The list of diseases would be established by an implementing act. This list, as well as the categories and their prioritisation, would be systematically reviewed, taking into account new scientific evidence. Measures are also provided for **emerging diseases**. A disease could be added urgently to the list of diseases. This should facilitate a timely response to new threats. The **responsibilities of all actors** dealing with animal health would be made explicit. Animal keepers, operators and animal professionals would be required to have an adequate level of **knowledge of animal health**, in order to increase awareness of potential threats.

Responsibilities for **notification, reporting and surveillance** of diseases at Member State and EU level would also be clarified (Part II), and the roles of operators, competent authorities and other actors set out. This also includes rules on animal health visits in establishments. Provisions would also allow for a **wider use of the compartment system**.

As part of the rules on disease awareness, preparedness and control (Part III) a **framework** would be explicitly provided for the **use of vaccination** for the prevention and control of certain diseases, together with rules on antigen, vaccine and reagent banks. More emphasis would be placed on **biosecurity at farm level**.

Provisions on registration, approval, traceability and movements would be brought together (Part IV), however laid down separately for terrestrial, aquatic and other animals. The basic principles, already provided for in current legislation, would be clarified and codified, such as: the registering and approval of establishments, responsibilities for registers and record keeping, **traceability requirements** (identification and registration systems), **requirements for movement, notification of movements**, and the content of **animal health certificates**. The new law would allow for **wider use of electronic certificates**.

Requirements with regard to entry into the EU and export would also be covered (Part V), with no major changes from existing legislation. Existing rules on **emergency measures** would be consolidated (Part VI) with only a few practical changes.

The final and transitional provisions (Part VII) would set out the conditions for adopting delegated acts and other necessary legal procedures and allow Member States to adopt additional or more stringent **national measures**.

For the majority of legislative acts currently in place,<sup>3</sup> the rules would be replaced, either by the regulation itself, or by subsequent Commission delegated or implementing acts. Consequently, existing legislative acts would be repealed. However, in order to ensure legal certainty regarding the application of rules for identification and registration of animals, disease control measures for certain zoonoses and non-commercial movements of pet animals, some acts<sup>4</sup> would continue to apply, until a date to be determined by a respective delegated act. Some further acts would also be repealed as being obsolete.<sup>5</sup> However, certain acts containing rules on transmissible animal diseases, including zoonoses, would remain in force after the adoption of the proposed regulation.<sup>6</sup> The proposed regulation would apply to zoonoses only if specific rules are not already laid down in those acts.

### Preparation of the proposal

Preparatory work for the proposal included an impact assessment and consultations which fed into it (discussions in the Animal Health Law Steering Group and in the [Animal Health Advisory Committee](#), as well as a web-based general stakeholders' consultation). The [Impact Assessment](#) was published on 6 May 2013, together with the proposal. The main problems with the existing legislation were identified (see 'Existing situation') and possible policy options assessed, of which the option 'a new flexible general legislative framework for animal health issues' was considered the most promising.

### Parliament's starting position

In 2008 the Parliament adopted a [resolution](#) on the new animal health strategy in which it advocated a single legal framework governing actions on animal health and supported the approach based on prevention.

### Stakeholders' views

[COPA-COGECA](#), the organisation representing EU farmers and agri-cooperatives, welcomed the objective of simplifying and clarifying the current legislation and reducing the large number of acts. It also published a [document](#) presenting the reaction of farmers and agri-cooperatives to the proposal and outlining its position on key issues. The [Federation of Veterinarians of Europe](#) was positive about the proposal and welcomed in particular the provisions on regular animal health visits to farms by veterinarians, considering them crucial to the prevention and early detection of

diseases. It also submitted its detailed [comments](#) on the proposal. The European Federation for Animal Health and Sanitary Security ([FESSASS](#)) welcomed the focus on prevention, the prioritisation of diseases and the simplification of legislation, but had concerns about the lack of clarity, and underlined that the harmonisation of the sanitary security level in the EU is an essential challenge and that the changes proposed will take time to implement.

### Advisory committees

The **European Economic and Social Committee** adopted, on 10 December 2013, its [opinion](#) on the proposals on animal health, plant health and plant reproductive material. It welcomed the introduction of consistent, transparent rules. With regard to the proposal on animal health it recommended some drafting changes to clarify the text. The EESC expressed reservations about the Commission's power to adopt delegated and implementing acts. It had concerns regarding the increased danger that wild animals migrating from third countries to the EU may spread transmissible diseases. It called on the Commission to provide for legislative measures and sufficient funding to avert this danger. Furthermore it presented a number of specific comments and called on the Commission to publish, as soon as possible, a list of animal diseases drawn up in close cooperation with Member States and other interested parties.

The **Committee of the Regions** [decided](#) not to issue an opinion.

### National parliaments

The subsidiary check deadline for the proposal was 3 July 2013, some 18 national parliaments [scrutinised](#) the proposal. The [Austrian Federal Council](#) submitted a reasoned opinion stating that the proposal is incompatible with the principle of subsidiarity. It asserted that the number of delegated acts is too large, which results in a lack of specificity and makes it impossible to assess the necessity and impact of the proposed measures. Three parliaments submitted contributions for political dialogue: The [Czech Senate](#) adopted and forwarded a resolution to the Commission, in which it expressed its opinion that the proposed scope of delegation of powers to the Commission is too extensive. The [French Senate](#) submitted a political opinion to the Commission on delegated acts, in relation to this and other proposals, in which it deplored the excessive use of these acts. Furthermore it adopted a resolution outlining its views on several points of the proposal, among others on the excessive resort to delegated and implementing acts. The [Italian Senate](#) in its resolution suggested, inter alia, that the list of diseases and species is an important element of the Regulation and should not be subjected to an implementing act. The issue of delegation of powers to the Commission was raised by several other national parliaments, even though they did not submit a reasoned opinion nor launch political dialogue.

### Parliamentary analysis

In September 2013, the Library of the European Parliament published a briefing '[A draft new animal health law for the EU. Some basics.](#)' presenting the proposal, its background, main issues related to animal health and EU policy in this area.

### Legislative process

On 6 May 2013, the Commission adopted the [legislative proposal](#) and submitted it to the Parliament and to the Council.

In Parliament, the proposal was [referred](#) (on 23 May 2013) to the Committee on Agriculture and Rural Development (AGRI) as the responsible committee and to the Committee on Fisheries (PECH) and the Committee on Environment, Public Health and Food Safety (ENVI) as committees for opinion. On 12 June 2013 Marit Paulsen (ALDE, Sweden) was appointed rapporteur. On 30 October 2013 she presented her [draft report](#). On 21 January 2014 the Committee on Legal Affairs (JURI) delivered its [opinion on the legal basis](#), in which it analysed the appropriateness of adding Article 13 TFEU (on animal welfare) to the legal basis of the proposal. The [opinion of the PECH committee](#) and [the opinion of the ENVI committee](#) were submitted on 27 January 2014 and on 30 January 2014 respectively. At its meeting of 11 February 2014, the AGRI Committee voted on the submitted amendments, on the amended proposal and on the draft legislative resolution which was adopted by a large majority (570 votes to 63 with 19 abstentions). The [committee report](#) was tabled for plenary on 19 February 2014.

On 14 April 2014 the Parliament held a joint [debate](#) on three proposals (on animal health, plant health and official controls). The vote in plenary took place on 15 April 2014: [Parliament's position at first reading](#) was adopted with 331 amendments to the Commission proposal. The main changes<sup>7</sup> concerned: amending the **title** of the regulation to reflect the fact that it deals with transmissible animal diseases and not with the broad topic of animal health in general; more **emphasis on prevention** (establishing of rules, instruments and mechanisms, division of responsibilities); taking account of **biodiversity; antibiotic resistance**; introducing a **list of diseases** in an annex; **border controls** (applying preventive measures on external borders); the link between **animal welfare** and animal and public health (references in the text and reference to Article 13 TFEU); **good animal husbandry** and **transport** of live animals; **stray animals**; **urgent measures** (possibility to adopt such measures by the Commission under close scrutiny of Parliament and Council); establishing a European network of **official animal health laboratories** and Union reference laboratories. On 9 September 2014 the Commission presented its [response](#), including a statement and justification of its position on Parliament's amendments.

In the Council, 36 working party meetings took place during the Irish, Lithuanian, Greek and Italian Presidencies. On 12 June 2014 the Greek Presidency presented a [progress report](#) on the state of play with regard to the animal health, plant health and official controls package. Concerning the proposal on animal health, main areas that needed further analysis were identified: the **listing of diseases and species** (in the view of the Presidency and most Member States, the lists should be included in the Regulation as annexes, not established separately by the Commission by an implementing act); **delegated acts** (while it was generally recognised that they ensured the flexibility necessary for amending elements of the Regulation in the future, the extent of the proposed empowerment of the Commission was examined carefully); repeal of the '**Pet Regulation**', i.e. Regulation (EC) No 576/2013 on non-commercial movements of pet animals (the intention of integrating health rules for all animal categories was generally supported, but the Presidency and some Member States had reservations about repealing the Regulation, as it had been only recently adopted).

In the new legislature, the AGRI Committee resumed the legislative work. At its meeting on 3 September 2014, it decided to launch interinstitutional negotiations in view of an early second agreement and on the nomination of a negotiating team. On 17 December 2014, the Council's Permanent Representatives Committee (Coreper)

agreed on the Presidency compromise text and mandated the incoming Latvian Presidency to negotiate an early second reading agreement with the Parliament.

Five trilogues were held under the Latvian Presidency (January-June 2015). On 1 June 2015 the co-legislators reached a provisional agreement on a compromise proposal text. The compromise was endorsed by Coreper on 10 June 2015.

On 17 June 2015, the AGRI Committee confirmed the agreement and its Chair addressed a letter to the President of Coreper stating that, if the Council adopts its position at first reading in accordance with the compromise, he would recommend to the Plenary that the Council's position be accepted without amendment at Parliament's second reading (early second-reading agreement).

At the AGRI meeting on 14 September 2015, the Committee Chair announced the retirement of Marit Paulsen, rapporteur of this dossier. She was replaced by Jasenko Selimovic (ALDE, Sweden).

On 14 September 2015, the General Affairs Council reached a political agreement endorsing the compromise text. On 14 December 2015 the Agriculture and Fisheries Council formally adopted [Council's position at first reading](#) by a large majority of 25 votes, with Austria and the United Kingdom voting against and Slovenia abstaining. These Member States issued [statements](#) on their decisions. **Austria** had reservations concerning the **list of diseases** which in its view it is the key element of the Regulation. It regretted that the approach taken in this regard does not ensure that diseases may be removed from the list by co-decision procedure. Austria also had concerns that certain diseases, covered for decades by additional guarantees, could be removed. The **United Kingdom** decided to oppose the Regulation because of the use of **delegated acts** to define technical details such as the list of diseases. **Slovenia** abstained from the vote, because, although it agreed with the majority of the provisions, it had concerns about the **list of diseases** and its update, which in Slovenia's view are the most important element of the act. It noted that the list is not up to date and that the updates should be carried out by an implementing act, not a delegated act.

#### **Some issues discussed and agreed during trilogue:<sup>8</sup>**

**Title of the regulation.** Proposed by the Parliament and slightly reworded by the Council, the new title would read: 'Regulation of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')'. It was agreed that this better corresponds to the scope and content of the proposal.

**Listing of diseases and species and categorisation of diseases.** In the initial proposal the lists of animal diseases and species covered by the Regulation would be established separately by the Commission by means of implementing acts. Implementing acts would also be used for categorising diseases into groups. The Parliament proposed to set out the lists of animals and species in annexes to the regulation. Amendments to the lists and the categorisation of diseases would be carried out by delegated acts. The Council shared the Parliament's view on listing of diseases and species in annexes, but proposed that five diseases (foot-and-mouth disease, classical swine fever, African swine fever, highly pathogenic avian influenza, African horse sickness) be included directly into the basic act. The final compromise text lists the five diseases in the basic act; other diseases, as well as species, are listed in annexes (Annex II with diseases was added),

amendable by delegated acts, while the categorisation of diseases is carried out by implementing acts. The list of diseases includes also **exotic diseases**.

**Delegated and implemented acts.** Both the Parliament and the Council noted the significant number of delegated and implemented acts provided for by the proposal and the extent of the elements they regulate. The general idea was not disputed by the co-legislators, as they acknowledged the need to amend certain provisions quickly in reaction to emergencies or new situations. The Parliament was, however, concerned about finding the right balance. The Council redrafted a significant number of articles to better describe the powers given to the Commission; some essential elements were introduced in the basic act.

A separate part on **non-commercial movements of pet animals** was added.

**Animal welfare.** The Parliament welcomed reflection of the close link between animal welfare and animal and public health in the Commission's proposal. It felt, however, that this approach should be reinforced, and proposed several amendments. The compromise text retains those that introduced a reference to Article 13 TFEU and more references to animal welfare into the text. At the request of the Parliament a [statement](#) on animal welfare was included in Commission's Communication from 15 December 2015 concerning the Council position at first reading.<sup>9</sup>

**Antimicrobial resistance.** The Parliament wanted greater stress on the problem of antimicrobial resistance in the recitals and in several articles. Furthermore it proposed to lay down an obligation for veterinarians and aquatic health professionals to raise awareness of this issue, as well as to make operators responsible for a prudent and responsible use of veterinary medicines. These amendments were taken into account. At the request of the Parliament two further [statements](#) were included in the Commission Communication mentioned above: a joint statement by the European Parliament, the Council and the Commission on antimicrobial resistance and the use of veterinary medicinal products, and a statement by the Commission on the regular reporting of the use of antimicrobial medicinal products in animals in the Union.

The Council position was announced in plenary on 21 January 2016. A draft report by the AGRI Committee with a draft [recommendation for second reading](#) and a draft legislative resolution was issued on 26 January 2016. At its meeting on 23 February 2016 the AGRI Committee adopted the draft recommendation. No amendments have been tabled.

The Parliament [voted](#) on this issue during the [plenary session](#) of 8 March 2016. The EFDD Group tabled a proposal to reject the Council position. This proposal was rejected by the plenary by 613 votes against, 78 for and 13 abstentions. The Council position was thereafter [approved](#) without a vote. The Regulation was thereby adopted. It enters into force 20 days after its publication in the [Official Journal](#) (which took place on 31 March 2016) and will apply from 21 April 2021.

## References

[Animal Health, 2013/0136\(COD\)](#), European Parliament, Legislative Observatory (OEIL).

[Proposal for a Regulation of the European Parliament and of the Council on Animal Health](#), COM(2013) 0260 final.

EP [press release](#) after the adoption of the Regulation, 8 March 2016.

[A draft new animal health law for the EU. Some basics](#), Weissenberger Jean, Library Briefing, Library of the European Parliament, 18 September 2013.

## Endnotes

- <sup>1</sup> [Regulation](#) (EU) no 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC.
- <sup>2</sup> Such as Council Directive 90/425/EEC, Regulation (EC) No 882/2004, Council Directive 64/432/EEC, and Regulation (EC) 854/2004.
- <sup>3</sup> For example: Council Directive 80/1095/EEC laying down conditions designed to render and keep the territory of the Community free from classical swine fever; Council Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine; Council Directive 82/894/EEC on the notification of animal diseases within the Community; Council Directive 92/119/EEC introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease. For the full list see Article 258 of the proposal.
- <sup>4</sup> Regulation (EC) No 1760/2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products; Regulation (EU) No 576/2013 on the non-commercial movement of pet animals; Council Regulation (EC) No 21/2004 establishing a system for the identification and registration of ovine and caprine animals; Council Directive 92/66/EEC introducing Community measures for the control of Newcastle disease; Council Directive 2000/75/EC laying down specific provisions for the control and eradication of bluetongue; Council Directive 2001/89/EC on Community measures for the control of classical swine fever; Council Directive 2002/60/EC laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever; Council Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease; Council Directive 2005/94/EC on Community measures for the control of avian influenza; Council Directive 2008/71/EEC on the identification and registration of pigs.
- <sup>5</sup> See Article 258 and Recital (156) of the proposal.
- <sup>6</sup> Regulation No 999/2001 on certain [transmissible spongiform encephalopathies](#); Directive 2003/99/EC on the monitoring of [zoonoses](#) and zoonotic agents; Regulation (EC) No 2160/2003 on the control of [salmonella](#) and other specified food-borne zoonotic agents; as well as Decision No 2119/98/EC setting up a network for the epidemiological surveillance and control of [communicable diseases](#) in the Community.
- <sup>7</sup> A [summary](#) of the changes introduced by the Parliament can be found in the European Parliament Legislative Observatory (OEIL).
- <sup>8</sup> A summary of the amendments proposed by the Parliament and the Council and of the outcome of negotiations is provided in the [Communication](#) from the Commission to the European Parliament pursuant to Article 294(6) of the Treaty on the Functioning of the European Union concerning the position of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on transmissible animal diseases (Animal Health Law), 15.12.2015, COM(2015) 638 final.
- <sup>9</sup> Ibid.

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