Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2013/0136(COD)
Procedure completed	

Transmissible animal diseases

Repealing Directive 98/99/EC 1998/0194(CNS)
Amending Regulation (EC) No 1760/2000 1999/0204(COD)
Repealing Directive 2002/99/EC 2000/0181(CNS)
Repealing Directive 2001/89/EC 2000/0214(CNS)
Amending Regulation (EC) No 2160/2003 2001/0177(COD)
Repealing Regulation (EC) No 21/2004 2002/0297(CNS)
Repealing Directive 2003/85/EC 2002/0299(CNS)
Repealing Directive 2004/68/EC 2003/0224(CNS)
Repealing Directive 2005/94/EC 2005/0062(CNS)
Repealing Directive 2006/88/EC 2005/0153(CNS)
Repealing Directive 2008/71/EC 2007/0294(CNS)
Repealing Directive 2009/156/EC 2008/0219(CNS)
Repealing Directive 2009/158/EC 2009/0067(CNS)
Repealing Regulation (EU) No 576/2013 2012/0039(COD)
Amended by 2013/0140(COD)

Subject
3.10.04 Livestock farming
3.10.08 Animal health requirements, veterinary legislation and pharmacy
3.10.08.05 Animal diseases
3.15.02 Aquaculture
3.70.01 Protection of natural resources: fauna, flora, nature, wildlife, countryside; biodiversity

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	AGRI Agriculture and Rural Development		12/06/2013
		ALDE SELIMOVIC Jasenko	
		Shadow rapporteur	
		PPE DORFMANN Herbert	
		S&D GIUFFRIDA Michela	
		Verts/ALE SMITH Alyn	
		EFD ZULLO Marco	
	Former committee responsible		
	AGRI Agriculture and Rural Development		12/06/2013
		ALDE PAULSEN Marit	
	Former committee for opinion		
	ENVI Environment, Public Health and Food Safety (Associated committee)		
	PECH Fisheries		12/06/2013
		Verts/ALE LÖVIN Isabella	

	Former committee for opinion on the legal basis		
	JURI Legal Affairs		10/01/2014
		S&D REGNER Evelyn	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	3437	14/12/2015
European Commission	Commission DG	Commissioner	
	Health and Food Safety	ANDRIUKAITIS Vytenis Povilas	
European Economic and Social Committee			
European Committee of the Regions			

Key events

06/05/2013	Legislative proposal published	COM(2013)0260	Summary
23/05/2013	Committee referral announced in Parliament, 1st reading		
21/11/2013	Referral to associated committees announced in Parliament		
11/02/2014	Vote in committee, 1st reading		
19/02/2014	Committee report tabled for plenary, 1st reading	A7-0129/2014	Summary
14/04/2014	Debate in Parliament		
15/04/2014	Decision by Parliament, 1st reading	T7-0381/2014	Summary
03/09/2014	Committee decision to open interinstitutional negotiations after 1st reading in Parliament		
17/06/2015	Approval in committee of the text agreed at early 2nd reading interinstitutional negotiations		
17/12/2015	Council position published	11779/1/2015	Summary
21/01/2016	Committee referral announced in Parliament, 2nd reading		
23/02/2016	Vote in committee, 2nd reading		
25/02/2016	Committee recommendation tabled for plenary, 2nd reading	A8-0041/2016	Summary
07/03/2016	Debate in Parliament		
08/03/2016	Results of vote in Parliament		
08/03/2016	Decision by Parliament, 2nd reading	T8-0067/2016	Summary
08/03/2016	End of procedure in Parliament		
09/03/2016	Final act signed		
31/03/2016	Final act published in Official Journal		

Technical information

Procedure reference	2013/0136(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Directive 98/99/EC 1998/0194(CNS) Amending Regulation (EC) No 1760/2000 1999/0204(COD) Repealing Directive 2002/99/EC 2000/0181(CNS) Repealing Directive 2001/89/EC 2000/0214(CNS) Amending Regulation (EC) No 2160/2003 2001/0177(COD) Repealing Regulation (EC) No 21/2004 2002/0297(CNS) Repealing Directive 2003/85/EC 2002/0299(CNS) Repealing Directive 2004/68/EC 2003/0224(CNS) Repealing Directive 2005/94/EC 2005/0062(CNS) Repealing Directive 2006/88/EC 2005/0153(CNS) Repealing Directive 2008/71/EC 2007/0294(CNS) Repealing Directive 2009/156/EC 2008/0219(CNS) Repealing Directive 2009/158/EC 2009/0067(CNS) Repealing Regulation (EU) No 576/2013 2012/0039(COD) Amended by 2013/0140(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114-p3; Treaty on the Functioning of the EU TFEU 043-p2; Treaty on the Functioning of the EU TFEU 164
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	AGRI/8/04856

Documentation gateway

Legislative proposal		COM(2013)0260	06/05/2013	EC	Summary
Document attached to the procedure		COM(2013)0264	06/05/2013	EC	Summary
Document attached to the procedure		SWD(2013)0160	06/05/2013	EC	
Document attached to the procedure		SWD(2013)0161	06/05/2013	EC	
Committee draft report		PE514.757	30/10/2013	EP	
Amendments tabled in committee		PE514.758	05/12/2013	EP	
Amendments tabled in committee		PE524.760	09/12/2013	EP	
Amendments tabled in committee		PE524.833	09/12/2013	EP	
Specific opinion	JURI	PE527.959	22/01/2014	EP	
Committee opinion	PECH	PE521.603	27/01/2014	EP	
Committee opinion	ENVI	PE521.493	30/01/2014	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0129/2014	19/02/2014	EP	Summary

Text adopted by Parliament, 1st reading/single reading		T7-0381/2014	15/04/2014	EP	Summary
Council statement on its position		14903/1/2015	09/12/2015	CSL	
Commission communication on Council's position		COM(2015)0638	15/12/2015	EC	Summary
Council position		11779/1/2015	17/12/2015	CSL	Summary
Committee draft report		PE575.379	26/01/2016	EP	
Committee recommendation tabled for plenary, 2nd reading		A8-0041/2016	25/02/2016	EP	Summary
Text adopted by Parliament, 2nd reading		T8-0067/2016	08/03/2016	EP	Summary
Draft final act		00007/2016/LEX	09/03/2016	CSL	
Follow-up document		COM(2021)0057	12/02/2021	EC	

Additional information

Research document	Briefing
National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2016/429
OJ L 084 31.03.2016, p. 0001 Summary

Corrigendum to final act 32016R0429R(01)
OJ L 057 03.03.2017, p. 0065

Corrigendum to final act 32021R0429R(05)
OJ L 048 11.02.2021, p. 0003

Final legislative act with provisions for delegated acts

Delegated acts

2019/3001(DEA)	Examination of delegated act
2019/3000(DEA)	Examination of delegated act
2020/2545(DEA)	Examination of delegated act
2020/2544(DEA)	Examination of delegated act
2019/3006(DEA)	Examination of delegated act
2019/3003(DEA)	Examination of delegated act
2020/2630(DEA)	Examination of delegated act
2018/2835(DEA)	Examination of delegated act
2019/2764(DEA)	Examination of delegated act
2021/2820(DEA)	Examination of delegated act
2021/2973(DEA)	Examination of delegated act
2021/2588(DEA)	Examination of delegated act

2021/2613(DEA)	Examination of delegated act
2021/2821(DEA)	Examination of delegated act
2021/2676(DEA)	Examination of delegated act
2020/2762(DEA)	Examination of delegated act
2020/2830(DEA)	Examination of delegated act
2021/2890(DEA)	Examination of delegated act
2021/2944(DEA)	Examination of delegated act
2021/2824(DEA)	Examination of delegated act
2023/2522(DEA)	Examination of delegated act
2023/2714(DEA)	Examination of delegated act
2023/2797(DEA)	Examination of delegated act
2023/2847(DEA)	Examination of delegated act
2022/2932(DEA)	Examination of delegated act
2022/2978(DEA)	Examination of delegated act
2023/2524(DEA)	Examination of delegated act
2023/2538(DEA)	Examination of delegated act
2022/2847(DEA)	Examination of delegated act

Transmissible animal diseases

PURPOSE: to lay down rules for the prevention and control of animal diseases, which are transmissible to animals or to human beings.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the current EU animal health legislative framework involves almost 50 basic Directives and Regulations and some 400 pieces of secondary legislation, some of them adopted as early as 1964. The main elements of the existing policy were drawn up largely between 1988 and 1995 when there were only twelve Member States.

New challenges, such as new diseases, have since emerged, and certain existing ones have reappeared. Trading conditions have also changed, with volumes of trade in animals and animal products increasing greatly, both within the EU and with third countries. There have, furthermore, been important scientific and technological developments, as well as important institutional changes within the EU.

A number of problems have been identified in regard to the existing legislation:

- with respect to the general policy approach:

  - the high complexity of the current Community Animal Health Policy (CAHP);

  - the lack of an overall strategy

  - an insufficient focus on disease prevention, with a particular focus on the need for increased biosecurity.

- with respect to the functioning of existing legislation:

  - issues related to intra-Union trade in live animals.

For the above reasons, the European Commission is proposing a single, comprehensive animal health law to replace the complex animal health rules currently in place.

This proposal is part of a comprehensive package that also includes three other proposals to modernise the plant health, plant reproductive material and official controls acquis.

IMPACT ASSESSMENT: the proposal is accompanied by an impact assessment. An evaluation of the CAHP in the last decade led to the adoption of the new EU Animal Health Strategy 2007-2013 (AHS) "Prevention is better than cure".

The AHS, which was welcomed by Parliament, provides for the adoption of a "single regulatory framework for animal health with a greater focus on incentives than penalties, consistent with other EU policies and converging to international standards" and which will "define and integrate common principles and requirements of existing legislation".

LEGAL BASIS: Articles 43, 114 and 168 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the proposal seeks to establish a single, simplified, transparent and clear regulatory framework that sets out systematically the objectives, scope and principles of regulatory intervention in the field of animal health.

Aim of the proposal: the proposal aims to improve standards and to provide a common system to better detect and control disease and tackle health, food and feed safety risks in a coordinated way. It seeks to focus on long-term preventative measures and working together with relevant stakeholders.

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

Notification and surveillance: the proposal clarifies the responsibilities for notification and surveillance, including animal health visits. It clarifies the roles of operators, competent authorities and others as regards surveillance of the animal health situation in the Union. Better use will be made of the synergies between surveillance undertaken by the different actors in the field to ensure the most effective and cost-efficient use of surveillance resources. Compartments, permitted only for Avian Influenza-related measures and in aquaculture at present, can now be used more widely. This allows more flexibility in disease control measures, introducing the possibility of continuing movements and trade under certain circumstances, considered from a risk-based perspective.

Disease Preparedness, Awareness and Control: the proposal continues to require Member States to draw up contingency plans for dealing with certain diseases, and to practise their implementation. It provides: (i) explicity for a regulatory framework for vaccination; (ii) rules for the use of antigen, vaccine and reagent banks; and (iii) rules on control measures to be taken in the case of suspicion of or confirmed disease outbreaks of certain diseases.

Requirements concerning Registration, Approval, Traceability and Movements: there would be distinct rules for terrestrial, aquatic, and other animals because of their different production methods and epidemiology. The proposal introduces the possibility for more animals to be registered and traced through electronic means, promoting simplicity and better regulation.

Imports and exports: the proposal sets out the standards and requirements for third countries in regard to animal imports, as well as requirements for exports. No practical changes from the existing legislation are envisaged.

Emergency Measures: these are considered a vital component of disease management and comprise the procedures to be followed in case of emergency, ensuring a rapid and consistent Union response. Only a few practical changes from the existing legislation are envisaged.

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

DELEGATED ACTS: the proposal includes provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union.

Transmissible animal diseases

The objective of ensuring a high level of health for humans, animals, and plants is enshrined in the Treaties underpinning the EU. Over the years, the EU has built up a comprehensive body of law designed to prevent and manage risks to animal and plant health and the safety of the food chain at EU and national level. The law in these policy areas is enforced by means of a common set of rules on official controls to be carried out by the competent authorities in the EU Member States.

To date, overall, the legal framework which the EU has developed has proven to be effective in preventing and countering risks. However, the modern global market increasingly exposes the EU to new risks and constantly calls for innovation and competitiveness. This, and the experience gained with EU law in this area, point to the need to simplify and update available instruments and to further integrate the approach across the different areas. The Commission has conducted a revision of the current legal framework for animal health, plant health, plant reproductive material and official controls aimed mainly at increasing effectiveness, consistency and legal clarity in those areas.

This Communication presents the resulting four legislative proposals in the four areas of animal health, plant health, plant reproductive material and official controls (the review package) and explains, for each of them, the current context, the rationale behind the package and the main improvements introduced. The package also includes a fifth proposal establishing a multiannual programme for EU financing of actions aimed at ensuring a high level of health for humans, animals and plants along the agri-food chain and in related areas while allowing businesses to operate in an environment that favours competitiveness and job creation.

Context of animal health in the EU: currently, EU intervention is focused on preventing and controlling transmissible diseases that may have significant health and economic impacts. The impact of an animal disease outbreak can vary widely, but it usually poses a direct risk to animal and often public health, partly through food of animal origin. However, there can also be indirect negative effects (possibly economic or social), including the cost to farmers and related industries of dealing with disease and of business disruption, the cost to the public sector of eradicating and monitoring the disease, and changes in consumption and international trade patterns.

Current EU animal health legislative framework: the EU animal health legislative framework consists of around 50 basic directives and regulations, some of which were adopted in the early 1960s. Since then, a body of over 400 veterinary acts - most of them drawn up between 1988 and 1995 for a Community of only 12 Member States - has been built up. In the meantime, new challenges have emerged: new diseases have sprung up, while others (e.g. foot and mouth disease, bluetongue and avian flu) have recently reappeared, reminding us of the serious risks they pose.

Trading conditions have also changed radically, with the volume of trade in animal products increasing significantly both within the EU and worldwide.

Content of the proposed Animal Health Law (AHL): the purpose of the proposal is (i) to ensure a high level of public health and food safety; (ii) to support farming and the rural economy; to improve economic growth, cohesion and competitiveness; and (iii) to promote farming practices and animal welfare which minimise environmental impacts.

The main driving principles of the revision process in this area are simplification, modernisation and increased consistency across the EUs animal health legislation.

The AHL lays down the foundations for a wide and comprehensive legislative framework for EU animal health policy. It clearly sets out the overarching principles and objectives necessary to further reduce animal disease while maintaining the EUs economic competitiveness. Detailed provisions (such as specific disease control measures, identification and registration rules for certain species, and specific measures on intra-EU movement for particular species) are to be dealt with by means of delegated or implementing acts. Using these acts to introduce more specific rules or requirements would allow decision-makers the flexibility and speed needed to react to rapidly changing scenarios and veterinary emergencies.

The proposed enhancement of disease surveillance, disease notification and reporting networks would better support early detection and control of diseases (including emerging diseases such as those linked to climate change) and ensure greater convergence with international standards.

Simplification and clarification: a legislative framework that is simplified and easier to understand would be more user-friendly for authorities and operators and would ensure their actions are more consistent and objective-focused. This has the potential to reduce the administrative burden on them by cutting down the time taken to familiarise themselves with the legislation and by introducing scope for simplifying certain administrative requirements and making them more coherent. The new AHL will clarify the animal health responsibilities of operators, veterinarians and others, partly by requiring a basic level of knowledge for the first time.

New technologies: the AHL will allow more scope for using new technologies for animal health activities such as monitoring pathogens, electronic identification and registration of animals and electronic certificates. The use of new technologies and systems will tend to reduce the administrative burden on both veterinary authorities and operators in their work.

Increased flexibility through the use of a risk-based approach: criteria for listing animal diseases, categorised systematically and on a scientific and evidential basis, will be introduced so that the EU can better prioritise the use of its resources, giving less priority to diseases which pose less risk. The wider use of compartmentalisation (i.e. where some farms are considered safe even during disease outbreaks), will allow a more risk-based approach to animal disease control and potentially fewer trade restrictions.

Transmissible animal diseases

The Committee on Agriculture and Rural Development adopted the report by Marit PAULSEN (ADLE, SE) on the proposal for a regulation of the European Parliament and of the Council on Animal Health.

The committee recommended that Parliaments position in first reading following the ordinary legislative procedure should amend the Commission position as follows:

Emphasis on prevention: Members felt that the regulation should be on the prevention and control of animal diseases which were transmissible among animals or to humans.

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

Measures taken should aim for (i) the effective functioning of the internal market, and food and feed safety; (ii) a reduction in the adverse effects on animal health, public health and the environment; (iii) reduction in certain diseases and risk factors leading up to diseases.

Biodiversity and the need to protect and conserve rare animal breeds, and to preserve genetic diversity should be taken into account.

Antibiotic resistance: Members proposed that Member States should pay particular attention to antimicrobial resistance and ensure better access to professional training in this area when designing their national plans for the prevention and control of infectious animal diseases.

Member States should take certain criteria into consideration, such as the detrimental effects of antimicrobial resistance, when determining whether or not to use veterinary medicinal products as disease prevention and control measures for a specific disease.

Generally, Members felt that the existing system should be supplemented by strategic measures to monitor, prevent and control infectious animal diseases, including those not listed in this regulation (the most resistant to antibiotics). These measures should include a requirement for a good animal husbandry and responsible use of veterinary medicines.

Animal welfare and animal health: Members stressed the well-established link between animal welfare and animal and public health. They made references to animal welfare in the text, since this has an influence on animal health such as when part of biosecurity measures. Moreover, an explicit reference was made to Article 13 of the Treaty on the Functioning of the European Union, in order to emphasise that animals are sentient beings.

Members also wanted to reiterate the importance of good animal husbandry and the requirements arising from EU legislation on animal transport. With respect to the movement of live animals, the Regulation should be amended to the effect that the deciding factors should be the journey time and the number of assembly operations, not whether the journey crosses a national border.

Stray animals: by 1 January 2018, Member States should introduce a registration requirement for dogs. The Commission shall submit by 31 July 2019 a report on the experience of the Member States with the registration and identification of dogs, with particular reference to stray animals.

Urgent measures: to tackle diseases that have a major impact on public health, agricultural production or animal welfare and health, the Commission must be empowered to adopt urgent measures. However, Members insist that both Parliament and Council must have proper scrutiny over the measures adopted and the possibility of repealing them if necessary.

Union reference laboratories: the Commission shall designate Union reference laboratories for illnesses for which, owing to their impact on health or the economy, this is necessary to achieve the objectives of the Regulation.

Transmissible animal diseases

The European Parliament adopted by 570 votes to 63 with 19 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on Animal Health.

Parliaments position in first reading following the ordinary legislative procedure amended the Commission proposal as follows:

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

Measures taken should aim for (i) the effective functioning of the internal market, and food and feed safety; (ii) a reduction in the adverse effects on animal health, public health and the environment; (iii) reduction in certain diseases and risk factors leading up to diseases.

Biodiversity and the need to protect and conserve rare animal breeds, and to preserve genetic diversity should be taken into account.

Antibiotic resistance: Members also proposed that Member States should pay particular attention to antimicrobial resistance and ensure better access to professional training in this area when designing their national plans for the prevention and control of infectious animal diseases.

Member States should take certain criteria into consideration, particularly the use of veterinary medicine on human health, such as the detrimental effects of antimicrobial resistance, when determining whether or not to use veterinary medicinal products as disease prevention and control measures for a specific disease.

Listed diseases: Parliament introduced a table of diseases of terrestrial animals in an annex to the regulation. The Commission will be empowered to adopt delegated acts, taking due account of the opinions of the European Food Safety Authority, and after due public consultation with stakeholders and experts, concerning amendments to the listed diseases.

Generally, Members felt that the existing system should be supplemented by strategic measures to monitor, prevent and control infectious animal diseases, including those not listed in this regulation (the most resistant to antibiotics). These measures should include a requirement for a good animal husbandry and responsible use of veterinary medicines.

Veterinarians or aquatic animal health professionals should immediately notify the competent authority in the event of an outbreak or suspicion of an outbreak of a listed disease. Doctors should immediately inform the competent authority of any sign of a zoonotic disease.

Border controls: Member States should, with technical assistance at Union level as regards listed diseases, ensure that appropriate preventive, risk-based biosecurity measures were applied along their external borders, in cooperation with the competent authorities of the third countries concerned.

Animal welfare and animal health: Parliament stressed the well-established link between animal welfare and animal and public health. They made references to animal welfare in the text, since this has an influence on animal health such as when part of biosecurity measures. Moreover, an explicit reference was made to Article 13 of the Treaty on the Functioning of the European Union, in order to emphasise that animals are sentient beings.

Members also wanted to reiterate the importance of good animal husbandry and the requirements arising from EU legislation on animal transport. With respect to the movement of live animals, the Regulation should be amended to the effect that the deciding factors should be the journey time and the number of assembly operations, not whether the journey crosses a national border.

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Urgent measures: to tackle diseases that have a major impact on public health, agricultural production or animal welfare and health, the Commission must be empowered to adopt urgent measures. However, Members insist that both Parliament and Council must have proper scrutiny over the measures adopted and the possibility of repealing them if necessary.

Union reference laboratories: the Commission should designate Union reference laboratories for illnesses for which, owing to their impact on health or the economy, this is necessary to achieve the objectives of the Regulation. Member States should designate one or more national reference laboratories for each Union reference laboratory designated.

Transmissible animal diseases

The Commission considers that the common position adopted by the Council with qualified majority reflects the original goals of the Commission's proposal and takes into account many concerns of the European Parliament.

To recall, the European Parliament adopted its position at first reading on 15 April 2014 and supported the main goals of the Commission's proposal. In particular, the European Parliament:

- expressed its support for the principle that prevention is better than cure and welcomed the attempt to bring together the current dispersed animal health legislation into one single set of principles;
- approved the scope of the proposed act, which is about transmissible animal diseases;
- welcomed the "one health" approach establishing a clear link between animal welfare and animal and public health.

The Commission indicated that it could accept in full, in part, in principle or subject to rewording 106 of the 331 amendments, proposed by the Parliament at first reading.

Following the adoption of the European Parliament's first reading position, informal discussions continued between the European Parliament, the Council Presidency and the Commission, with a view to concluding an agreement at the common position stage ('early second reading agreement').

1) Amendments incorporated in full or in part in the position of the Council at first reading:

- proposed new title for the proposal to better describing its focus on transmissible animal diseases;
- categorisation of animal diseases and emerging diseases;
- proposed the retention of Regulation (EC) No 1760/2000 on bovine identification and beef labelling, which the animal health proposal aimed to repeal;
- ensure that animal welfare is taken into account when considering or implementing animal health measures.

2) Amendments rejected by the Commission and incorporated in full, in part or in principle in the position of the Council:

Listing of animal diseases:

- The European Parliament proposed to eliminate the Commissions implementing powers enabling to establish the list of animal diseases and species to which the rules in the Regulation apply, and the categorisation of diseases into different groups according to which measures are appropriate for them. The European Parliament proposed to list the diseases in an Annex to the Regulation, but to provide the Commission with delegated powers to amend or supplement that list.
- The Council proposed that a short list of five significant diseases is written into the enacting part of the Regulation, but that the listing of the remaining of diseases, as well as the categorisation of all the listed diseases, and listing of species, should be done through implementing acts. The Council also added more criteria for the listing and categorisation of animal diseases, which in their view added the missing essential elements to the enacting part of the Commission proposal.
- The Parliament recognised the value of these additional essential elements providing more detailed criteria for disease listing and categorisation. It also agreed to the proposed list of five diseases and to the possible listing of other diseases in an Annex amendable by delegated act, while implementing powers were preserved for the categorisation of animal diseases.

Consultation with stakeholders and scientists:

- The European Parliament required several types of specific consultation when drawing up delegated acts. Contrary to Article 290 (2) TFEU, some of those amendments set out a legally binding obligation for the Commission to conduct these consultations.
- The Commission cannot accept the amendments of the European Parliament which are contrary to Article 290(2) of TFEU. However, it can agree to the wording in the Council position whereby it would consult experts, stakeholders and the European Food Safety Authority, as well as engage in wider public consultations, when and as appropriate.

Review clause (report by the Commission):

- Parliament asked the Commission to submit a report on the impact of the Regulation by 31 December 2019. The Council also requested a reporting obligation in a recital or in an Article, while avoiding any unnecessary administrative burden.

Animal welfare:

- Some amendments on animal welfare were accepted by the Council while others went further providing animal welfare rules, thus interfering with the existing animal welfare legislation. Also, all amendments that were overlapping or inconsistent with the existing requirements - or putting at risk animal and public health - were not incorporated in the Council's position. The Commission supports this position.
- The European Parliament could eventually drop or adjust several of its amendments but asked the Commission for a commitment to take future action for the protection of animals through a statement on animal welfare. The Commission exceptionally agreed to make a statement.

Antimicrobial resistance:

- Amendments obliging actors to consider or raise awareness on the risks of antimicrobial resistance are acceptable, while amendments interfering with the legislation on veterinary medicines cannot be supported as they go beyond the scope of this proposal.
- Parliament also insisted on setting up a responsibility of operators for a responsible use of veterinary medicines as in their view such a clear obligation was needed in the EU legislation to establish a link with the proposal on veterinary medicines. The Council accepted in principle this amendment and was supportive of the joint statement by the European Parliament, Council and the Commission on the antimicrobial resistance.
- The Commission also agreed, as a compromise, to make a statement on the regular reporting on the use of veterinary antimicrobial medicinal products.

Other professionals and professional bodies carrying out certain tasks on behalf of the competent authority:

- The European Parliament requested that certain professionals, such as bee health professionals, would be recognised on the same basis as veterinarians and that certain other qualified individuals or professional bodies would be allowed to carry out certain tasks.
- The Council addressed the same questions by opening the possibility for Member States to authorise other professionals for certain tasks while taking into account the subsidiarity principle enabling Member States to take their own decisions concerning authorisation based on the existing national structures.

Animal health laboratories:

- The European Parliament envisaged requirements for official animal health laboratories. The Commission cannot agree with these amendments. In a spirit of a compromise, the Council proposed a new Article linking the laboratory requirements in the animal health and official controls proposals.

3) Amendments of the European Parliament rejected by the Commission and not incorporated in the position of the Council: these concern amendments which seek to:

- provide that Member States adopt strategic measures for diseases, including those that are assessed as not relevant for the Union and therefore not listed for Union intervention;
- regulate the use of the veterinary medicinal products in the Union;
- allow a Member State to restrict the movements of animals or products if the Member State itself judges that it is scientifically justified and necessary to prevent the introduction or spread of any disease;
- define stray, feral or non-kept animals as different categories from wild animals;
- set up a compulsory registration of all dogs and, when appropriate, set up a database;
- retain the Regulation (EU) No 576/2013 on the non-commercial movement of pet animals which was to be repealed by the animal health proposal;
- retain Regulation (EC) No 21/2004 on ovine and caprine identification and registration, and Directive 2008/71/EC on pig identification and registration;
- introduce a new category of "kept aquatic animals" thus separating aquaculture and other kept aquatic animals.

4) New provisions introduced by the Council: the Council's position was considered acceptable to the Commission regarding the new provisions on transitional periods, the transitional measures (recognition of acquired rights) and the registration obligation of certain operators conducting assembly operations.

In conclusion, although on certain elements the common position differs from the Commission's original proposal, the Commission considers that it represents a carefully balanced compromise and is satisfied that it covers all issues considered essential by the Commission when adopting its proposal.

Transmissible animal diseases

The Council adopted its position at first reading with a view to the adoption of a 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.

The regulation lays down provisions on the prevention and control of animal diseases which are transmissible among animals or to humans and amending and repealing certain acts in the area of animal health. It aims to:

- ensure high standards of animal and public health in the Union;
- implement the commitments and visions provided for in the Commission's Communication on animal health strategy including the "one health" principle;
- consolidate the legal framework for a common Union animal health policy through a single, simplified and flexible regulatory framework for animal health.

The main amendments made in the Councils position are as follows:

Delegated and implementing powers: the proposed act will constitute a framework Regulation that will empower the Commission to determine a significant amount of its details by delegated and/or by implemented acts. While the Council did not change the principle of a framework Regulation, a large number of Articles were redrafted in order to better circumscribe the powers conferred on the Commission. Essential elements were introduced in the basic act in a number of cases.

Listing of diseases: disease-specific rules for the prevention and control of diseases provided for in the regulation shall apply to:

- the following five listed diseases: (i) foot and mouth disease; (ii) classical swine fever; (iii) African swine fever; (iv) highly pathogenic avian influenza; (v) African horse sickness; and
- the listed diseases set out in the list in Annex II.

The Councils position strengthens the criteria in the basic act regarding the review of the listed diseases in Annex II and provides that the Commission will adopt the amendments necessary with reference to the criteria (by delegated act) at the latest 24 months before the date of application of the regulation.

Criteria for categorising the listed diseases: the categorisation of listed diseases, i.e. the application of disease prevention and control rules to each of those diseases, may be done by the Commission by implementing acts. In order to make the process of categorisation more predictable and transparent, the Council added more details to the proposed criteria, introduced new criteria and made those criteria binding. It also agreed that the criteria for the categorisation could only be amended by ordinary legislative procedure.

The categorisation process should be based on predefined criteria such as the profile of the listed disease in question, the level of its impact on animal and public health, animal welfare and the economy of the Union, the risk of its spreading and the availability of disease prevention and control measures in respect of that listed disease.

Emerging diseases: a disease other than a listed disease shall be considered to be an emerging disease provided it has the potential to meet the criteria for listing diseases and: (i) results from the evolution or change of an existing disease agent; (ii) is a known disease spreading to a new geographic area, species or population; (iii) is diagnosed for the first time in the Union; or (iv) is caused by an unrecognised or a previously unrecognised disease agent.

The Commission shall, by means of implementing acts, take the necessary measures regarding an emerging disease.

Transitional periods: to allow for more time to implement the legislation, the Council proposed an overall transitional period of 60 months. It also requested additional transitional measures, such as those obliging the Commission to adopt certain key delegated acts at least 24 months before the date of application of the Regulation and for other delegated and implementing acts to determine a period of at least six months between the adoption of the initial set of such acts and their application.

Transitional measures (recognition of acquired rights): the Council introduced new Articles providing the operators and Member States with the possibility of recognising rights as regards the approval or registration of existing operators and establishments, the approved

disease free statuses, and the special provisions for salmonella.

Registration obligation of certain operators conducting assembly operations: the Council position added provisions concerning the registration obligation of certain operators without establishments conducting transactions with animals that may have an impact on traceability of those animals.

Non-commercial movements of pet animals: Regulation (EU) 576/2013 sets out a simplified procedure for movements of pet animals when they are considered as non-commercial movements according to that Regulation. In order to ensure the stability of the rules of that Regulation, the Council agreed that, while it should be repealed by this Regulation, it should continue to apply for 10 years. The Council also included most of its elements in the basic act.

Transmissible animal diseases

The Committee on Agriculture and Rural Development adopted the recommendation for second reading contained in the report by Jasenko SELIMOVIC (ADLE, SE) on the Council position at first reading with a view to the adoption of a 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").

The committee recommended that the European Parliament should approve the Council position at first reading. It also approved the joint statement by Parliament, the Council and the Commission on antimicrobial resistance and the use of veterinary medicinal products, annexed to this resolution.

Based on the Communication from the Commission entitled "Action plan against the rising threats from Antimicrobial Resistance", this joint statement called upon the Member States to commit themselves to collect relevant, comparable and sufficiently detailed data on the actual use of antimicrobial medicinal products in animals and to send such data to the Commission in order to ensure a more prudent use of antimicrobial medicinal products in animals, hence contributing to the reduction of the risk of antimicrobial resistance.

Members also took note of two Commission statements in which the Commission:

- undertakes to publish a regular report as regards the use of antimicrobial medicinal products in animals in the EU on the basis of data made available by the Member States;
- affirms that it is fully committed to paying full regard to animal welfare (although the proposed Regulation does not contain specific provisions on animal welfare), including ensuring full implementation and appropriate development of this legislation.

Transmissible animal diseases

The European Parliament adopted a resolution on the Council position at first reading with a view to the adoption of a 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").

Parliament approved the Council position at first reading. It also approved the joint statement by Parliament, the Council and the Commission on antimicrobial resistance and the use of veterinary medicinal products, annexed to this resolution.

Based on the Communication from the Commission entitled "Action plan against the rising threats from Antimicrobial Resistance", this joint statement called upon the Member States to commit themselves to collect relevant, comparable and sufficiently detailed data on the actual use of antimicrobial medicinal products in animals and to send such data to the Commission in order to ensure a more prudent use of antimicrobial medicinal products in animals, hence contributing to the reduction of the risk of antimicrobial resistance.

Members also took note of two Commission statements in which the Commission:

- undertakes to publish a regular report as regards the use of antimicrobial medicinal products in animals in the EU on the basis of data made available by the Member States;
- affirms that it is fully committed to paying full regard to animal welfare (although the proposed Regulation does not contain specific provisions on animal welfare), including ensuring full implementation and appropriate development of this legislation. The Union has a well-developed acquis regarding animal welfare covering different species (broilers, laying hens, pigs, calves) or activities (farming, transport, slaughter, research, etc.). This animal welfare legislation will necessarily continue to apply.

Transmissible animal diseases

PURPOSE: to introduce a single piece of legislation to regulate animal health in the Union, based on the principle that "prevention is better than cure" in order to better detect and control diseases, as well as to tackle safety risks in a coordinated way.

LEGISLATIVE ACT: Regulation (EU) 2016/429 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)

CONTENT: the Regulation establishes provisions relating to the prevention and control of animal diseases that are transmissible to animals or to human beings. It aims to improve standards and to provide a common system to better detect and control diseases, as well as to tackle health, food and feed safety risks in a coordinated way.

Scope: the Regulation applies to: (a) kept and wild animals; (b) germinal products; (c) products of animal origin; (d) animal by-products and derived products; (e) facilities, means of transport, equipment and all other paths of infection and material involved or potentially involved in the spread of transmissible animal diseases.

Objectives: the new provisions relate to:

· the prioritisation and categorisation of diseases of Union concern and for the establishment of responsibilities for animal health: the provisions on prevention and control of the diseases will apply to: (a) the five following listed diseases: (i) foot and mouth disease; (ii)

classical swine fever; (iii) African swine fever; (iv) highly pathogenic avian influenza; (v) African horse sickness; and (b) the listed diseases set out in the list in Annex II; (c) emerging diseases;

- the early detection, notification and reporting of diseases, surveillance, eradication programmes and diseasefree status;
- disease awareness, preparedness and control;
- the registration and approval of establishments and transporters, movements and traceability of animals, germinal products and products of animal origin within the Union;
- the entry of animals, germinal products, and products of animal origin into the Union and the export of such consignments from the Union
- noncommercial movements of pet animals into a Member State from another Member State or from a third country or territory;
- the emergency measures to be taken in the event of a disease emergency situation.

The measures aim to ensure: (i) improved animal health to support sustainable agricultural and aquaculture production in the Union; (ii) the effective functioning of the internal market; (iii) a reduction in the adverse effects on animal health, public health and the environment of certain diseases and the measures taken to prevent and control diseases.

They must take into account:

- the relationship between animal health and: (i) public health; (ii) the environment, including biodiversity and valuable genetic resources, as well as the impact of climate change; (iii) food and feed safety; (iv) animal welfare, including the sparing of any avoidable pain, distress or suffering; (v) antimicrobial resistance; (vi) food security;
- the economic, social, cultural and environmental consequences arising from the application of disease control and prevention measures;
- relevant international standards.

Delegated and implementing powers: the act constitutes a framework Regulation, which will empower the Commission to determine a significant amount of the details by delegated and/or by implemented, acts. Implementing powers to lay down disease prevention and control measures for emerging diseases is conferred on the Commission. The latter may adopt delegated acts regarding amendments to the list of diseases in Annex II or regarding the restrictions on, prohibitions of or obligations to use certain veterinary medicinal products within the framework of the control of certain listed diseases.

Transitional period: the Regulation provides a general transitional transition period of 60 months (until 21 April 2021).

The requirements set out in the Regulation will not apply until the key delegated and implementing acts have been adopted by the Commission, allowing a period of 24 months from the adoption of the key acts until the date when they start to apply, thus permitting Member States and operators to duly adapt to the new rules. In addition, the Regulation provides for a period of at least 36 months for the Commission to elaborate the new rules.

ENTRY INTO FORCE: 20.4.2016. The Regulation is applicable from 21.4.2021.

DELEGATED ACTS: the Commission may adopt delegated acts in order to amend the non-essential elements of the Regulation. The power to adopt such acts is conferred on the Commission for a period of five years from 20th April 2016 (which may be tacitly extended for the same period). The European Parliament or Council may raise objections to a delegated act within two months of the date of notification (which may be extended by three months). If Parliament or Council raise objections, the delegated act may not enter into force.