Council of the European Union

Brussels, 5 January 2016
(OR. en)

5013/16

Interinstitutional File:
2013/0136 (COD)

AGRI 1
VETER 1
AGRILEG 1
ANIMAUX 1
SAN 1
CODEC 1

COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	15 December 2015
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2015) 638 final
Subject:	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)

Delegations will find attached document COM(2015) 638 final.

Encl.: COM(2015) 638 final

EUROPEAN
COMMISSION

Brussels, 15.12.2015
COM(2015) 638 final

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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)

(Text with EEA relevance)

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(Text with EEA relevance)

1. BACKGROUND

Date of transmission of the proposal to the European Parliament and to the Council (document COM(2013) 260 final – 2013/0136 COD):	6 May 2013.
Date of the opinion of the European Economic and Social Committee:	10 December 2013.
Date of the position of the European Parliament, first reading:	15 April 2014.
Date of transmission of the amended proposal:	[*].
Date of adoption of the position of the Council:	14 December 2015.

* Taking into account the developments in the informal discussions between the Council and the European Parliament following the European Parliament's first reading, the Commission did not prepare an amended proposal but expressed its views on the Parliament's amendments in the "*Communication de la Commission sur les suites données aux avis et résolutions adoptés par le Parlement européen lors des sessions d'avril I et II 2014"* (document SP(2014) 471 of 9 July 2014).

2. OBJECTIVE OF THE PROPOSAL FROM THE COMMISSION

The objective of the Commission proposal is to introduce a single piece of legislation to regulate animal health in the Union, based on the principle that "prevention is better than cure". The proposal 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.

This enhanced system will give operators working in the food chain, such as farmers and veterinarians, the capability to react quickly and to limit the spread of a disease and minimise its impact on animals and consumers.

Furthermore, the proposal introduces the categorisation, prioritisation and listing of diseases which require intervention at Union level, enabling a more risk based approach and appropriate use of resources.

Sufficient flexibility is provided to adjust the animal health measures to different establishments and local circumstances, in particular with respect to requirements for the registration and approval of establishments and for the keeping of animals and products.

On a broader scale, the Union as a whole is working towards the objectives of the Europe 2020 strategy. The proposal on animal health supports these crucial overarching objectives by reducing the risk of the negative economic, social and environmental impacts of poor animal health or animal disease outbreaks; and consequently by supporting the economic security and success of animal keepers, particularly farmers, and thus contributing to smart, inclusive and sustainable growth.

Finally, the legal framework needs to be flexible yet robust enough for an effective Union response in the event of important climate changes, as well as new and unknown emerging risks, and to allow for quick adjustment to scientific developments and new international standards.

3. COMMENTS ON THE POSITION OF THE COUNCIL

3.1 General comments

The Commission's proposal was transmitted to the European Parliament and to the Council on 6 May 2013. 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. It also recognised the scope of the proposed act, which is about transmissible animal diseases, and welcomed the "one health" approach establishing a clear link between animal welfare and animal and public health. In addition, the European Parliament called for a balance between predictability and flexibility. The position of the European Parliament included 331 amendments to the Commission's proposal.

No modified Commission's proposal was issued. In its Communication to the European Parliament, the Commission indicated that it could accept in full, in part, in principle or subject to rewording 106 of the 331 amendments, as they would clarify or improve the Commission's proposal and were consistent with its general aims. Due to the absence of the Council’s position at the time and in order not to prejudge the Commission’s role in facilitating agreement between the co-legislators at a later stage, the Commission's position on the Parliament amendments remained rather conservative and tended towards defending the Commission’s proposal.

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').

These discussions proved successful and are reflected in the common position of the Council, which was adopted by qualified majority on 14 December 2015.

3.2 Amendments of the European Parliament accepted by the Commission and incorporated in full, in part or in principle in the position of the Council at first reading

Title of the proposal: the European Parliament suggested a new title for the proposal to better describing its focus on transmissible animal diseases. The Council, in its position, agreed and proposed a slight rewording. Due to the political importance of the new title and the fact that the proposal indeed focuses on transmissible animal diseases, the Commission accepts the change.

Categorisation of animal diseases and emerging diseases: the European Parliament proposed in its amendments 83-87 new wording clarifying the groups of categories of animal diseases provided for in Article 8 of the Commission's proposal. The Council incorporated those amendments into its position subject to some rewording. This clarification is acceptable for the Commission.

On emerging diseases, the European Parliament in its amendments 176 and 177 requested to take more and clearer measures. However, those amendments were not ideally placed in the text. The Council shared the concerns of the European Parliament about the clarity of measures for emerging diseases and proposed a new Article. This compromise, addressing the concerns of both co-legislators, is acceptable for the Commission as it provides for clearer rules to deal with emerging diseases.

Repeal of Regulation (EC) No 1760/2000 on bovine identification and beef labelling: the European Parliament proposed in its amendments 38, 324 and 328 the retention of Regulation (EC) No 1760/2000 on bovine identification and beef labelling, which the animal health proposal aimed to repeal. The Commission clarified that even though the proposal had indicated that the entire Regulation (EC) No 1760/2000 would be repealed, the Commission's intention was not to repeal parts that concern labelling of beef and beef products. This issue was also discussed in the Council which suggested a change to the proposal to reflect it. The Commission agrees with the Council's position and therefore accepts the retention of Title II of Regulation (EC) No 1760/2000, which concerns labelling of beef and beef products and is outside the scope of the animal health proposal.

Moreover, the European Parliament pointed out that recently amended Article 22 of the Regulation (EC) No 1760/2000 provided for fixed control intensity for identification and registration of bovine animals. The Commission believes that such descriptive provisions are unnecessary as they are provided for in the Commission's proposal for a Regulation on official controls (COM (2013) 265, 2013/0140/COD).

Nonetheless, the European Parliament wanted to obtain re-assurances that equal level of controls would be kept in the future for bovine animals which is reflected in a new recital.

Animal welfare: the European Parliament required in its amendments 5, 99 and 202 that animal welfare is taken into account when considering or implementing animal health measures. The Commission's proposal already required that animal welfare is systematically taken into account when considering the impacts of diseases and measures to combat diseases. The amendments of the European Parliament that were reinforcing this intention were considered acceptable by the Commission and were supported by the Council.

3.3 Amendments of the European Parliament rejected by the Commission and incorporated in full, in part or in principle in the position of the Council at first reading

Listing of animal diseases: the European Parliament proposed, in a series of amendments (in particular amendments 13, 14, 65-67, 70-72, 76, 77, 80-82, 88-90) to eliminate the Commission's implementing powers under Articles 5, 7 and 8 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 (amendment 331).

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 (related to Articles 5 and 8 respectively), 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. The Parliament also agreed to the proposed list of five diseases in Article 5 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 (following Article 8).

While the Commission had originally rejected the above-mentioned amendments of the European Parliament, it could accept the Council's and the Parliament's final position as a compromise, which preserves the necessary efficiency, flexibility and legal certainty for the listing and categorisation of diseases and listing of species.

Consultation with stakeholders and scientists: the European Parliament, in its amendments 41, 66, 75, 77, 82, 157, 260 and 322, 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 Council in its position wanted to recognise the importance of the Commission's consultation with experts, including Member States' experts, and amended the proposal accordingly. The Council also supported the Parliament on the involvement of stakeholders in the consultation.

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): amendment 330 of the European Parliament asked, in an Article, 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.

The Commission was initially not in favour of this additional reporting duty as there are other tools, such as fitness checks and evaluations, to judge the impact of EU legislation. Besides, the original timeframe was too short. As part of the overall compromise, the Commission can accept the amendment proposed by the European Parliament, subject to rewording provided for in the Council's position.

Animal Welfare: the European Parliament originally requested a number of amendments on animal welfare. Some were accepted by the Council (see point 3.2) while others (for example amendments 173, 180, 194 and 257) went further providing animal welfare rules, thus interfering with the existing animal welfare legislation and potentially undermining disease control measures in emergency situations. The Council is firm on the separation between animal health and animal welfare and opposes these amendments broadly sharing the Commission views. 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. As part of the overall agreement, the Commission exceptionally agreed to make a statement.

Antimicrobial resistance: the European Parliament adopted several amendments on antimicrobial resistance. Antimicrobial resistance was already covered in the Commission's proposal through provisions on the resistance to treatments and on the disease profile. Amendments obliging actors to consider or raise awareness on the risks of antimicrobial resistance are acceptable (Amendments 73, 101), while amendments interfering with the legislation on veterinary medicines cannot be supported as they go beyond the scope of this proposal.

The European Parliament also insisted on the adjustment of Article 9 (amendment 94) 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 (COM(2014) 558, 2014/0257 (COD)).

Eventually, the European Parliament was willing to give up other amendments on antimicrobial resistance and veterinary medicines, but requested in return a joint statement by the European Parliament, the Council and the Commission on antimicrobial resistance, and a Commission statement on the regular reporting on the use of antimicrobial medicinal products in animals in the Union.

The Council accepted in principle amendment 94 and was supportive of the joint statement. The Commission can agree to amendment 94 as reworded in the Council's position, support the joint statement on the antimicrobial resistance and, as a compromise, 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 (amendments 103 and 110) and that certain other qualified individuals or professional bodies would be allowed to carry out certain tasks (amendments 19 and 109).

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. This is in line with the Commission's views that tasks can be delegated to other professionals as long as this is in line with international standards and subsidiarity and proportionality are respected.

Animal health laboratories: the European Parliament envisaged (amendments 150-155) requirements for official animal health laboratories, including provisions on the laboratory network and requirements on the official laboratories as well as national and Union reference laboratories. The Commission cannot agree with these amendments because the tasks and responsibilities of those laboratories are covered in the proposal for a Regulation on official controls.

The Council broadly shared the Commission's view and has, as a compromise, proposed a new Article linking the laboratory requirements in the animal health and official controls proposals. In a spirit of a compromise, this solution is acceptable for the Commission.

3.4 Amendments of the European Parliament accepted by the Commission in full, in part or in principle, but not incorporated in the position of the Council at first reading

Some small issues were accepted by the Commission in part, but were not specifically included in the final Council position as in the course of the negotiations they had become redundant or were already explained elsewhere or implicitly included in the proposal (for example amendments 4, 8, 26, 45, 156, 222 and 277).

3.5 Amendments of the European Parliament rejected by the Commission and not incorporated in the position of the Council at first reading

Member State's strategic measures for non-listed diseases: the European Parliament required (amendments 29 and 107) that strategic measures are taken by Member States for diseases, including those that are assessed as not relevant for the Union and therefore not listed for Union intervention.

The Council did not incorporate the European Parliament's amendment as this provision goes beyond the scope of the proposal and would create unjustified administrative and financial burden for Member States. The Commission supports the Council's position as strategic measures for non-listed diseases are a matter of subsidiarity.

Veterinary medicinal products: the Parliament's amendments 94, 159, 160, 162 and 163-165 regulate the use of the veterinary medicinal products in the Union in a way that interferes with the existing legislation on veterinary medicines and entails significant overlaps with Commission proposal on veterinary medicines. The Council could therefore not accept these amendments. The Commission shares the Council's position.

National measures: the European Parliament proposed amendments 37, 268 and 323, which 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. This went further than the current system of 'additional guarantees', retained in the Commission proposal, whereby the Commission approves for a limited number of diseases the additional guarantees for intra-Union trade requested by a Member State, which has decided to eradicate on an optional basis one or more of those diseases.

The Council proposed amendments which clarify the 'additional guarantees', and enable the Member States to take their own disease prevention and control measures. The Commission considers the Council's position a suitable compromise as it meets to some extent the European Parliament's concerns while preserving the principles of the Single Market.

'**Non-kept', stray and feral animals:** several amendments of the European Parliament (amendments 49, 51, 53, 74, 198-201, 203, 211-215, 218) aimed to define stray, feral or 'non-kept' animals as different categories from 'wild' animals. The Parliament*'s* concern was that those categories of animals should not be excluded from Union legislation.

The Commission's proposal made a clear distinction between 'kept animals' and 'wild animals' and animal disease prevention and control rules that could be applied to animals kept under human control and those applied to animals that are not under human control. In this context, stray or feral animals, including those of species normally domesticated, are considered as 'wild animals'. Defining those animals as a separate category could cause confusion, legal uncertainty and potentially restrict the measures that can be taken with respect to them.

The Council accepted the logic of the Commission's proposal and added some clarifications including a full Part on non-commercial movements of pet animals, which distinguishes the movements of animals kept for companion purposes from stray and other animals. The Commission is in support of those solutions, which follow the line of its proposal and add clarity.

Identification and registration of dogs: the European Parliament required, in amendment 236, all Member States to set up a compulsory registration of all dogs and, when appropriate, set up a database. The Commission's proposal provided for a legal basis for the possible future introduction of identification and registration requirements of different animal species, possibly including dogs. The Council supported the Commission's proposal since requiring all Member States to set up such a system, without a proper impact assessment, may be disproportionate to the animal health risk and could entail financial and administrative burden for an unidentified benefit.

Non-commercial movements of pet animals: several amendments of the European Parliament (amendments 36, 39, 40, 54, 239-244, 246-247, 263-267 and 325) entail the retention of the Regulation (EU) No 576/2013 on the non-commercial movement of pet animals (the "Pet Regulation"), which was to be repealed by the animal health proposal.

The intention of the Commission's proposal was to integrate all relevant animal health rules for all animal species and categories under one set of rules. This would ensure that animals such as dogs and cats could be dealt with in a coherent manner from an animal health perspective, whether they are kept or stray animals, and whether they are traded commercially or moved for non-commercial purposes as pets.

Both the Council and the European Parliament had reservations about repealing the Pet Regulation so soon after its adoption. The Parliament took the view that the Pet Regulation should continue to be in place. The Council's position was that the non-commercial movement of pets logically fitted into the animal health framework, but that the Pet Regulation should not be re-opened so soon after its adoption. Therefore, it proposed a 10 year period of application for the Pet Regulation together with a set of rules in the animal health proposal matching those laid down in the Pet Regulation and replacing them after the 10 year application period.

The Council's position is a good compromise towards the European Parliament's position and the Commission can therefore support it.

Retaining legislation on identification and registration of pigs and ovine and caprine animals: the European Parliament, in its amendments 238, 326 and 327, asked to retain Regulation (EC) No 21/2004 on ovine and caprine identification and registration, and Directive 2008/71/EC on pig identification and registration.

The Commission proposed to repeal the current identification and registration legislation so that all animal health issues come under one set of general principles. It was the Commission's intention to retain the spirit and details of that legislation and to provide stability for Member States and for operators while at the same enabling more flexibility for the adoption of new technologies, adaptation to new challenges and the provision of derogations in low risk situations. The Council has, in its position, supported the Commission's proposal.

Aquatic animals, changes in definitions related to aquaculture: the European Parliament suggested amendments 50, 291-296, 300-304, 306 and 307 introducing a new category of "kept aquatic animals" thus separating 'aquaculture' and other 'kept aquatic' animals. The Commission proposal made a distinction between 'kept animals' and 'wild animals' where aquaculture animals were considered as kept aquatic animals. The Council has tried to meet the Parliament's concern without undermining the original intention of the Commission proposal by clarifying the definition of aquaculture animals and making clearer which disease prevention and control rules apply to aquaculture and which to 'wild aquatic' animals. The Commission can therefore support the proposed Council's solutions.

3.6 New provisions introduced by the Council

Transitional periods: the Council expressed concerns about the amount of legislation that would be repealed and replaced by this new animal health framework. To allow for more time to implement the legislation, the Council proposed an overall transitional period of 60 months instead of 36 as proposed by the Commission. 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.

The Council's position is acceptable for the Commission as a general compromise and also taking into account the time needed to develop the supporting delegated and implementing legislation. The European Parliament did not object this requirement.

Transitional measures (recognition of acquired rights): the Council introduced new Articles providing the operators and Member States with the possibility to recognise rights as regards the approval or registration of existing operators and establishments, the approved disease free statuses, and the special provisions for salmonella. These additions are acceptable for the Commission as they ensure that the existing rights are automatically carried over to the new legal framework thereby helping to avoid unnecessary administrative burden and costs for the operators and competent authorities and providing legal certainty in the transitional period. The European Parliament supported those changes.

Registration obligation of certain operators conducting assembly operations: the Council in its 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. The Commission could accept these additions as they contribute to overall traceability and are coherent with the requirements of the existing animal health legislation. The European Parliament has supported those changes.

4. CONCLUSION

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. 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.

5. STATEMENTS

5.1 Statement by the Commission on animal welfare

This Regulation lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans and does not contain provisions which regulate specifically animal welfare, albeit animal health and welfare are linked. 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.

The Commission is fully committed to paying full regard to animal welfare in accordance with Article 13 of the Treaty and within the limits set out therein, including ensuring full implementation and appropriate development of this legislation.

5.2 Joint statement by the European Parliament, the Council and the Commission on antimicrobial resistance and the use of veterinary medicinal products

The Communication from the Commission to the European Parliament and the Council – Action plan against the rising threats from Antimicrobial Resistance[1] – emphasises the preventive role of the Regulation on transmissible animal diseases ("Animal Health Law") and the consequent expected reduction of the use of antibiotics in animals. In addition to the requirements of this Regulation, Member States are called upon 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.

5.3 Statement by the Commission on the regular reporting on the use of antimicrobial medicinal products in animals in the Union

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.

[1] COM (2011) 748.