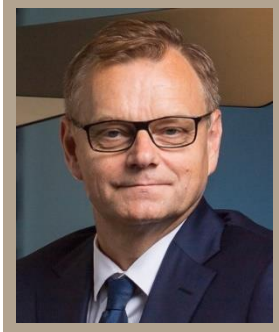
EU NEWS

May 2022

UEVP

Union Européenne des Vétérinaires Praticiens – AISBL
Union of European Veterinary Practitioners – AISBL



The ongoing discussions on mirror clauses reached a new milestone this month. Following the publication of its report, the European Commission presents the existing European and international regulations concerning the use of antibiotics in animals, as well as the Commission's ambitions on the subject. This step forward therefore provides information on the measures envisaged concerning veterinary medicinal products which could have an impact on our profession.

Furthermore, the fight against antimicrobial resistance continues, as highlighted by the recent exchange between the European Commission and the MEPs. A subject that we will actively participate in and continue to follow closely.

In parallel, several measures have been taken at European level to contain the spread of diseases in livestock, including avian influenza and African swine fever.

Finally, the European mobilisation in favour of animal welfare is still important, as illustrated by two open letters calling on the European Commission and the Council to take action to eliminate intensive breeding methods.

Piotr KWIECIŃSKI, UEVP President

TABLE OF CONTENTS

PRIORITY ISSUES

Latest EU institutional news

Latest developments on the CAP reform

On 1st June, the European Commission submitted for consultation its draft implementing act and its annexes on the evaluation of national strategic plans (NSPs).

This text specifies the principles and information to be transmitted annually to the European Commission so that it can monitor the implementation of NSPs in the Member States. In the annex, the European Commission proposes a list of "success factors" to measure the achievement of the nine specific objectives of the CAP.

This public consultation will close on 30 June. The adoption of this implementing act is expected in the fourth quarter of 2022.

Update on EMA activities

Decisions of the Committee for Medicinal Products for Veterinary Use (CVMP)

The Committee for Medicinal Products for Veterinary Use (CVMP) held a meeting from 10 to 12 May 2022.

The Committee adopted a positive opinion for a marketing authorization application for **Bonqat**, a new product for the alleviation of acute anxiety in cats.

The Committee adopted a positive opinion for a type II variation application concerning quality-related changes for **Simparica Trio**, as well as two positive opinions for a type IB variation grouped application for **Vectra 3D** and **Vectra Felis**.

Following a referral procedure for injective veterinary medicinal products containing vitamin A for use in food producing species, the Committee agreed that the withdrawal periods for milk, meat and offal derived from treated food producing species should be amended. The Committee adopted by consensus an opinion recommending regulatory and risk mitigation measures to provide assurance for consumer and user safety.

The Committee adopted one clarification report relating to scientific advice previously provided for a pharmaceutical product for dogs and cats.

Following one request for limited market classification and eligibility, the CVMP classified an immunological product for cattle. The product is eligible for financial incentives as it is tented for use in food producing species.

Regarding pharmacovigilance, the Committee reviewed the Periodic Safety Update Reports (PSURs) for **Cytopoint, Draxxin** and a signal detection outcome for **Osurnia,** and concluded that changes to their product information were required.

The Committee also reviewed a Periodic Safety Update Reports (PSURs) for **Circovac, Clynav, Miratraz, Panacur AquaSol, Posatex** and **Spironolactone Ceva** and concluded that no further action was required.

The Committee adopted a revised procedure for **nomination and appointment of co-opted members**.

Latest news on mirror clauses at EU Level

The European Commission publishes its report on the "Application of EU health and environmental standards to imported agricultural and agri-food products"

The European Commission published on 3 June, 2022 its report on "*the application of EU health and environmental standards to imported agricultural and agri-food products*", which aims to identify actions that the EU is already taking at the international level - both multilaterally and bilaterally - but also "*autonomously*", to address global environmental concerns or citizens' expectations regarding imported agricultural or agri-food products, with a focus on the application of health and environmental standards to imported products, including animal welfare.

It should be noted that the European Parliament and the Council had requested that the Commission produce this report at the end of the negotiations on the reform of the Common Agricultural Policy (CAP) in June 2021.

A provisional version of this report was released in May 2022, which included similar content and conclusions. Similarly to its draft, the report refers to the regulation of growth promoters antibiotics :

- It is recalled that Regulation 2019/6 on veterinary medicinal products, which applies since January 2022, provides for several measures to combat antimicrobial resistance, including Article 118 of the Regulation on the use of antimicrobials in animals and animal products intended for import into the EU. According to this article, animals and animal products intended for import into the EU must not be treated with antimicrobials for the purpose of growth promotion, or to increase yield with antimicrobials designated in the EU as being reserved for the treatment of certain infections in humans.
- The report emphasizes that measures to promote "*more prudent and responsible*" use of antimicrobials in animals should support the goal of the Farm to Fork strategy to reduce overall antimicrobial sales in the EU for farm animals and aquaculture by 50% by 2030.
- At the international level, within free trade agreements, there is usually collaboration and information exchange to promote the "*prudent and responsible*" use of antibiotics in livestock and veterinary practices. In this regard, the report states that the EU encourages the phasing out of the use of antibiotics as growth promoters.
- It is also highlighted that the Farm to Fork strategy sets the objective of ensuring "*an ambitious sustainability chapter in all EU bilateral trade agreements*". On this point, the report states that the new chapter on sustainable food systems (SFS) integrated into certain trade agreements includes provisions for cooperation in the field of food science, animal welfare and the fight against antimicrobial resistance. The report underlines that the European Commission will continue to propose a chapter on sustainable food systems in future EU trade agreements, and that such a chapter has already been agreed with Chile and is being negotiated with Australia, Indonesia and New Zealand.
- Reference is also made to the EU-UK Trade and Cooperation Agreement - negotiated following Brexit - which includes specific binding provisions ensuring a level playing field, with commitments to non-regression of levels of protection in various areas, for example in relation to managing the environmental impacts of agricultural or food production, including through the use of antibiotics.

The report concludes by stressing that the EU is able to take action "*autonomously*" where necessary to address global environmental concerns or animal welfare issues. It also states that before applying production standards to imports, a case-by-case assessment is essential, depending on the area.

In conclusion of this report, the Commission invites the Council and the European Parliament to examine the conclusions and orientations set out in the report and to take them into account in their future discussions. It should be noted that this report is non-binding, but it allows the foundations to be laid, particularly the legal ones, on reciprocity measures. In practice, it also establishes a progress report on the subject, on which the Council and the European Parliament could respectively present their positions.

The report will be presented at the Special Committee on Agriculture (SCA) on June 7, 2022 and at the Agriculture and Fisheries Council on 13 June 2022.

Latest news on antibiotics at EU Level

Exchange of views on the draft implementing act concerning the list of antimicrobials for human use

At the meeting of the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) on 11 May 2022, Claire Bury, Deputy Director General for Food Sustainability in the European Commission's Directorate General for Health and Food Safety (DG SANTE) presented the European Commission's draft implementing act including the list of antimicrobials to be reserved for human use.

As a reminder, while this draft implementing regulation should establish a list of antimicrobials or groups of antimicrobials that will be reserved for the treatment of infections in humans, a previous delegated act published in the EU's Official Journal in October 2021, sets out the criteria for the designation of antimicrobials that should be reserved for the treatment of certain infections in humans.

In her intervention on 11 May 2022, the representative of the European Commission presented the content of the draft implementing act, including

- A "*clear*" statement that the antimicrobials listed in the text may not be administered to animals and that there are no exceptions to this list.
- Antimicrobial medicines should not be administered routinely or used to compensate for poor hygiene, inadequate breeding, lack of animal care or to compensate for poor farm management.
- Several references to "*strict*" rules on prophylactic and metaphylactic treatment of animals.
- A "*clear*" statement that if new scientific data or information on antimicrobial use emerges, the list will be revised.

The representative of the European Commission also clarified that colistin - which is subject to "*strict requirements*" according to Claire Bury - is not listed in the draft implementing act, in particular due to the decrease in sales of colistin, and the decrease in its use in the EU Member States.

Furthermore, during her intervention, the representative of the European Commission indicated that during an exchange between the Member States and the European Commission in the Standing Committee on Veterinary Medicinal Products on 4 April 2022, a strong majority of Member States supported the proposed list and encouraged the Commission to act swiftly on the matter.

Claire Bury also indicated that the European Commission had also opened a public consultation on the draft implementing regulation, which closed on 17 May.

Following Claire Bury's presentation, the majority of MEPs interventions were rather unfavourable to the text proposed by the European Commission:

- Peter LIESE (EPP, Germany), Martin HÄUSLING (Greens/EFA, Germany) and Anja HAZEKAMP (The Left, Netherlands) - vice-chair of the ENVI committee - insisted in particular on the important risk of antimicrobial resistance.
- Sara CERDA (S&D, Portugal) stressed that the proposed text does not encourage a reduction in the use of antibiotics
- Nicolae ŞTEFĂNUȚĂ (RE, Romania) felt that there were not enough antibiotics mentioned on the list, and indicated the need to find new financial and incentive models to support research and development for the next generation of antimicrobials for human and veterinary use.

In contrast to the MEPs on the ENVI Committee, Norbert LINS (EPP, Germany) - Chairman of the European Parliament's Committee on Agriculture and Rural Development (AGRI) - who was present at the exchange of views, was in favour of the text proposed by the European Commission.

In her response to MEPs' interventions, the European Commission representative stressed notably that the proposed list of antimicrobials will be applied to EU imports, and that part of the budget of the *"EUforHealth"* programme (i.e. 15 million euros) would be used for the fight against antimicrobial resistance.

Claire Bury also said that the European Commission was preparing a Council recommendation on antimicrobials. On this point, MEP Bas EICKHOUT (Greens/EFA, The Netherlands) - vice-chair of the ENVI committee - pointed out that the proposal for a recommendation should also be addressed to the European Parliament, so that it can use its control power on this issue.

The European Commission must now finalise the draft implementing act and publish it in the coming weeks. Thereafter, according to a specific procedure and very strict criteria, the European Parliament has the possibility to potentially object to the Commission's implementing act.

Latest news on animal health

Conclusions on vaccination of poultry against avian influenza in the Council of the European Union

On 24 May, European Agriculture Ministers met and approved the draft conclusions to ensure the development of vaccination against avian influenza prepared by the French Presidency of the Council of the European Union (PFUE).

Vaccination is presented as a "*complementary tool*" to the "*strict application of biosecurity measures*" and surveillance. The PFUE also recognises the various obstacles to its widespread deployment, including concerns that vaccinated poultry could not be exported to third countries. However, the European Commission and Member States are called upon to "*intensify their efforts to develop and implement vaccination strategies [...] focusing on species and farming practices at risk*" and to "*improve the acceptability of vaccination in international trade*".

In the Council debate, several Member States - including Germany and Spain - stressed the importance of ensuring that the development of vaccination does not have a negative impact on European exports. For their part, Denmark, Germany, Estonia and Sweden requested a cost/benefit study.

In response, the European Commissioner for Health and Food Safety, Stella KYRIAKIDES, welcomed the Council's conclusions. She said that the European Commission has been developing rules on vaccination against avian influenza since last year, which will be adopted in the second half of the year. The European Commission will give a mandate to the European Food Safety Authority (EFSA) to "*complete the lack of experience and scientific knowledge*".

New countries listed among the Annex to the Implementing Act on emergency measures due to outbreaks of highly pathogenic avian influenza

On 11 May, the European Commission adopted the amendment to the Annex to the Implementing Act 2021/641 concerning emergency measures due to outbreaks of highly pathogenic avian influenza in certain Member States.

The European Commission confirms that a feasibility study under Regulation 2019/6 on veterinary medicinal products will have to be carried out. The European Commission explains its delay by the fact that it has been focusing on the finalisation of the delegated and implementing acts necessary for the implementation of this regulation.

In order to establish measures to control highly pathogenic avian influenza (HPAI), this implementing act establishes protection and surveillance zones for Member States following outbreaks of HPAI, which are to be listed in the Annex to the implementing decision.

In order to establish measures to control highly pathogenic avian influenza (HPAI), this implementing act establishes protection and surveillance zones for Member States following outbreaks of HPAI, which are to be listed in the Annex to the implementing decision.

Therefore, Bulgaria, France, Hungary, the Netherlands and Poland have recently been added to this list. The European Commission has examined the disease control measures taken by the above mentioned Member States, in collaboration with the national competent authorities, and has been able to ensure and confirm that the boundaries of these protection and surveillance zones are at a sufficient distance from holdings keeping poultry or captive birds where recent outbreaks of HPAI have been confirmed.

Adoption of the European Parliament resolution on the introduction of transitional rules on the packaging and labelling of veterinary medicinal products

On 5 May, the European Parliament adopted a legislative resolution on the proposal for a regulation laying down transitional rules for the packaging and labelling of authorised veterinary medicinal products in accordance with Directive 2001/82 (on veterinary medicinal products) and Regulation 726/2004 (laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use).

As a reminder, the European Commission published a proposal for a regulation in March of this year to address concerns about the practical application of Regulation 2019/6 (on veterinary medicinal products) which came into force on 28 January 2022. For this reason, the European Commission considered that immediate steps should be taken to resolve interpretation problems and legal uncertainties in order to avoid possible disruptions in the supply of veterinary medicines. In this context, transitional rules **until 29 January 2027** have been proposed, allowing marketing authorisation holders to market veterinary medicinal products that comply with the packaging and labelling requirements of the previous legislation.

In response, the European Parliament amended the European Commission's draft proposal so that the transitional measures would also apply to veterinary medicinal products "which are authorised **or registered**".

Special measures by the European Commission regarding African Swine Fever cases in Italy and Germany

On 4 May, Italy informed the European Commission about the African Swine Fever situation on its territory following an outbreak of the disease in feral pigs in the municipality of Rome. Subsequently, Germany also informed the European Commission about an outbreak of African Swine Fever in the Land Baden-Württemberg, which was confirmed on 25 May.

As a result, and in order to prevent any disruption of trade within the European Union, the competent authorities in Italy and Germany were required to establish an infected zone and a restricted zone respectively, in accordance with Delegated Regulation (EU) 2020/687 and Implementing Regulation (EU) 2021/605.

In view of the importance of the Italian case, the area is now subject to special control measures against African swine fever, including the suspension of the movement of shipments of pigs kept and products from the area to other Member States and to third countries. This decision applies until 31 August 2022 but will be reviewed at the next meeting of the Standing Committee on Plants, Animals, Food and Feed. As regards the decision on Germany, these exceptional measures apply until 25 August 2022.

The European Commission declines the proposal of some Member States for a new EU legislative framework establishing a "positive list" for keeping pets

At the Agriculture Council on 24 May, several ministers made a request to the European Commission to provide a new European legislative framework for a European "*positive list*" of species that can be kept as pets by private individuals.

This request, initially from Cyprus, was supported by the Lithuanian, Luxembourg and Maltese delegations.

In response, "*the introduction of an EU-wide positive list would represent a systemic change, raise issues of compatibility with the World Trade Organisation (WTO) and be very difficult to implement",* argued the European Commissioner for Health and Food Safety, Stella KYRIAKIDES. "*There is also no scientific evidence to support such an approach*", she added. The EU Commissioner concluded her speech by stressing: "*We are therefore not entirely convinced that a list would be more effective than the wide range of existing policy and legislative instruments*".

Monitoring of inorganic arsenic in animal feed

On 20 May, the European Commission published a recommendation concerning the monitoring, by Member States and the active participation of feed business operators, of the presence and levels of inorganic arsenic in animal feed.

According to Directive 2002/32/EC, which sets maximum levels for arsenic in a wide range of feed, it should be noted that the maximum levels refer to total arsenic, as at the time the levels were set there was no standard method for the separate analysis of inorganic arsenic and it was only possible to systematically analyse the total arsenic content.

For the European Commission, it is now appropriate to determine the ratio of inorganic arsenic to total arsenic. For this purpose, the European Commission recommends the collection of samples of the following feed materials and compound feeds:

- Grass meal from grass, from dried lucerne and from dried clover;
- Dried (sugar) beet pulp and dried (sugar) beet pulp (molasse) ;
- Palm kernel expeller;
- Fish and other aquatic animals and products derived thereof;
- Seaweed meal and feed materials derived from seaweed;
- And compound feed containing fish, other aquatic animals and products derived thereof and/or seaweed meals and feed materials derived from seaweed.

Finally, the European Commission calls on Member States to ensure that the results of the analyses are communicated to the European Food Safety Authority (EFSA) at regular intervals, and at the latest by 30 June 2023.

OTHER ISSUES

Latest news on animal welfare

Publication of a study on CAP-induced measures and instruments to improve animal welfare and reduce antimicrobial use by the European Commission

On 11 May, the European Commission published a study evaluating the effects of the Common Agricultural Policy (CAP) over the period 2014-2020 on animal welfare and antimicrobial use.

"*While there are no indicators to document progress in the implementation of sub-measures and types of operations focusing on animal welfare or antimicrobial use*", the report explains, the information gathered and interviews with stakeholders have highlighted "*the limited effect of the CAP on animal welfare at EU level*", confirmed the European Commission. However, the report also underlined that examples of 'successful' changes in practices, notably in animal husbandry conditions and animal health management practices, have been observed.

In view of this, the authors of the study recommended the establishment of a set of specific animal welfare indicators (in close collaboration with stakeholders) on the one hand, and the setting of quantified targets on the use of antimicrobials, aiming to "*reflect the efforts of each Member State to comply with the 'Farm to Fork' strategy"* on the other.

Publication of an open letter calling on the European Commission to ban the use of the equine chronic gonadotropin (eCG) method in intensive agriculture

In an open letter to the European Commission, twenty European animal welfare organisations have called for a ban on the production, import and use of equine chronic gonadotropin (eCG) (also known as Pregnant Mare Serum Gonadotropin (PMSG)).

This hormone - extracted from the blood of pregnant mares - is used in intensive agriculture to increase the reproductive performance of farm animals, such as pigs, sheep, goats and cattle. According to the surveys cited, eCG production has been shown to cause serious animal welfare problems and raises a number of concerns. For example, in Europe, eCG is mainly used to increase fertility in pigs. However, this implies a short recovery time between litters and the birth of too many litters, causing the animals to be slaughtered early.

However, these European associations point out that several alternatives to eCG are available on the European market, making this hormone dispensable. Therefore, the open letter calls on the European Commission to :

- Communicate on the production of eCG in the EU;
- Acknowledge that this method violates EU legislation on animal testing;
- Ban the production, import and use of eCG.

Publication of an open letter calling on the Council to support a ban on the crushing and gassing of chicks and ducklings at EU level

Following the formation of a European coalition of some twenty animal welfare organisations, an open letter to the Council was sent on Wednesday 1 June. These associations called on EU agriculture ministers to support a ban on the systematic gassing and crushing of male chicks and female ducklings.

It is estimated that "*each year in the EU, hundreds of millions of male chicks from the laying hen industry and tens of millions of female ducklings from the foie gras industry are culled, because they are considered as an industry by-product which does not generate profit*". However, the co-signatories consider that this culling is not necessary because "*sex selection methods, well before hatching, have been developed and are already implemented in some Member States*".

This initiative, driven by France and Germany, wants the ban to be extended to the whole of the European Union and to include ducklings in its scope. In France, only the killing of male chicks in the laying hen sector is concerned.

With the support of

EURALIA

info@euralia.eu