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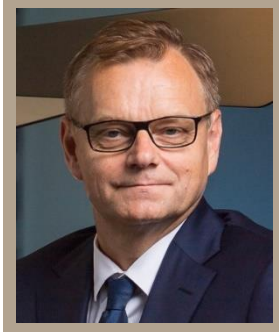
UEVP

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



This month, the fight against antimicrobial resistance and the harmonization of the use of veterinary vaccination is once again at the heart of European issues. In particular, measures have been taken concerning the ban on growth promoting antibiotics in imports, and the legal framework for the implementation of vaccinations under the legislation on transmissible animal diseases.

The priorities for the European Commission include:

- *prepared a proposal for a Council recommendation on antimicrobial resistance that will address national action plans that may allow for further guidance of practices;*
- *published a proposal for a monitoring plan for the early detection of zoonotic pathogens;*
- *continued to ensure the update of special control measures against African swine fever in Europe;*
- *and monitored indicators, including that of veterinary drug residues.*

On this last point, the recent indications have concluded that there has been a further general decrease in residues of veterinary drugs in products of animal origin, which can be considered encouraging.

With regard to animal welfare, two new secondary legislations have also been adopted concerning the transport of animals at sea and recommendations were made to promote cage-free poultry farming.

Piotr KWIECIŃSKI, UEVP President

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PRIORITY ISSUES

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 14th to 16thFebruary 2023.

The Committee adopted several positive opinions for variation requiring assessment to align the product information with version 9.0 of the QRD template for: **Bravecto Plus, Zeleris, Aservo EquiHaler, Simparica Trio, Librela, Innovax-ND-IBD, Evanovo, Gumbohatch, Zolvix, BTVPUR, Galliprant** and **Trocoxil, Procox.**

The Committee adopted several positive opinions for variation requiring assessment concerning quality-related changes for **Mhyosphere PCV ID, Syvazul BTV**, **Librela, Halocur, Equip WNV, Purevax RCP FeLV, Purevax RCP**, **Suvaxyn PRRS MLV, Naxcel, Suprelorin, Equip WNV**, **Versican Plus Pi/L4R; Versican Plus Pi/L4; Versican Plus DHPPi/L4; Versican Plus DHPPi/L4R; Versican Plus L4**, **Vectormune FP ILT** and **Vectormune FP ILT + AE.**

The Committee adopted a positive opinion for a grouped variation requiring assessment for **Suvaxyn PRRS MLV** concerning the addition of nasal use as an additional route of administration and to modify the approved therapeutic indication to include protection against heterologous subtype-1 AUT15-33, subtype-2 BOR57 and subtype-3 Lena strains of the PRRS virus.

The Committee adopted a positive opinion for a variation requiring assessment for **Lotilaner Elanco** (*lotilaner*) concerning the change of classification from 'subject to veterinary prescription' to 'not subject to veterinary prescription'.

The Committee adopted several positive opinions for marketing authorisations applications for **Bovilis Nasalgen-C, Coxevac, Innovax-ILT-IBD, Eurican L4** and **Prolevare**.

The Committee concluded two referral procedures for **Catophos 100 mg/ml + 0.05 mg/ml solution** for injection for horses, cattle, dogs and cats and associated names and **Vey Tosal 100 mg/ml+0.05 mg/ml solution** for injection for horses, cattle, dogs and cats and associated names.

The Committee adopted five scientific advice reports further to four requests for initial advice and one follow-up advice. One request concerned a biological product and four concerned pharmaceutical products. The respective target species were dogs, horses, sheep and cattle.

The Committee adopted a draft guideline on plasmid DNA vaccines for veterinary use for a 4-month period of public consultation.

The Committee adopted two revised VICH pharmacovigilance guidelines: one on electronic standards for transfer of data and the other on data elements for submission of adverse event reports.

Latest news on antimicrobial resistance at EU level

Publication of the delegated act by the European Commission on the ban of growth-promoting antibiotics in imports

On 27th of February, the European Commission published a delegated act on the ban of growth-promoting antibiotics in imports.

The text, which completes the legislation on veterinary medicinal products in force since 2019, provides for a ban on the import of animals having received 1) growth-promoting antibiotics or 2) included in the list of medicinal products reserved for human use.
This delegated act was subject to public consultation and notification to the World Trade Organisation (WTO).

However, the European Commission still has to establish an implementing act with a list of "**approved third countries**" authorised to export products of animal origin to the European Union, as well as an implementing act on specific requirements for certification of compliance. Thus, the new prohibition rules will only apply two years after the adoption of this list of approved third countries.

The delegated act is now submitted to the Council and the European Parliament for review, which have two months to express any objections. If they have no objections, the delegated act enters into force.

Preparation by the European Commission of a proposal of a Council Recommendation on antimicrobial resistance in the context of National Action Plans

Following the parliamentary question of MEP Dolors MONTSERRAT (EPP, Spain) to the European Commission on the EU's response to the shortage of antimicrobials and the consequences of antimicrobial resistance, the European Commission replied on 3rd February.

Indeed, while the European Health Emergency Preparedness and Response Authority (HERA) - *a Directorate-General of the European Commission created in September 2021* - identifies antimicrobial resistance as one of the three main health threats requiring close coordination in the EU, Dolors MONTSERRAT (EPP, Spain) questioned the European Commission on its recommendations for dealing with the phenomenon of antimicrobial shortages, on the supervision of national plans, and on the measures put in place to prevent and counteract shortages of paediatric amoxicillin (one of the main antibiotics for respiratory diseases).

In its response, the European Commission refers to the **2017 EU Action Plan on Antimicrobial Resistance**, in which it supports the implementation and development of national action plans through joint country visits with the European Centre for Disease Prevention and Control, the publication of a review of national action plans and a new joint action co-funded by the EU4Health funding programme.

The European Commission also highlighted the ongoing preparation of a **proposal for a Council Recommendation on antimicrobial resistance that will address national action plans.** This initiative, **expected by the end of March 2023**, will tackle notably the issue of antimicrobial resistance and will aim to overcome market failures in the development of new antimicrobials and ensure their prudent use.

Furthermore, it is mentioned that HERA is cooperating closely with Member States to **monitor the current shortages of amoxicillin, investigate the causes and coordinate mitigating measures.**

Publication of a joint analysis by EFSA and ECDC on antimicrobial resistance

On 6th March 2023, the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) published a report entitled *"The European Union Summary Report on Antimicrobial Resistance in zoonotic and indicator bacteria from humans, animals and food in 2020/2021".*

The findings of the study carried out between 2013 and 2021 state that, in general, resistance to the most important antimicrobials is low, with the exception of the resistance of *Salmonella* and *Campylobacter* which are antimicrobials often used to treat humans and animals.

More specifically, the report points out :

- An increase in resistance of *Salmonella Enteritidis* and *Campylobacter jejuni* to ciprofloxacin in humans. Indeed, the level of ciprofloxacin resistance against important Campylobacter is so high that it is no longer recommended for human uses.
- The decrease in resistance of *Campylobacter jejuni* to erythromycin in broilers.
- In addition, it was noted that resistance of *Escherichia coli to* carbapenem is still rare in animals. However, the report stresses that this resistance need to be continuously monitored and studied.

Latest news on animal health

EFSA report concludes that veterinary drug residues in animal products have decreased in 2021

In an annual report published on 23rd February, the European Food Safety Authority (EFSA) concluded that there has been a **further general decrease in residues of veterinary medicines in products of animal origin.**

This report presents the results of analyses carried out in 2021 on just over 600,000 samples of products of animal origin, submitted by the Member States of the European Union, Iceland, Norway and the United Kingdom (Northern Ireland).

The report summarises the presence of residues of veterinary medicinal products and other substances such as environmental contaminants in live animals and animal products. It covers several types of veterinary substances including antibacterial and hormones.

The percentage of non-compliant samples continues to fall, from 0.19% in 2020 to 0.17% in 2021, the lowest figure in the last twelve years.

Compared to the results of 2017, 2018, 2019 and 2020, in 2021 the frequency of non-compliant results was decreased for antithyroid agents, while for steroids and resorcylic acid lactones the frequency of non-compliant results was higher than in 2020, but lower compared to the previous years.

For prohibited substances, compared to 2020 the frequency on non-compliance results in 2021 was higher, although consistent with that of 2017 and 2018.

Decreases compared to all previous years were noted for other substances and environmental contaminants, chemical elements (including metals) and dyes. On the opposite, a significant increase compared to all previous years was found for "other substances".

Harmonisation of animal vaccination rules with the publication of a European Commission Delegated Act in the Official Journal of the European Union

The European Commission announced on 20th February 2023 **a harmonisation of the rules on the vaccination of animals against the most serious animal diseases.**

Following the adoption by the European Commission of the delegated act concerning the rules applicable to the use of certain veterinary medicinal products for the prevention and control of listed diseases, it was published in the Official Journal of the European Union on 20 February 2023 and will enter into force on 12 March 2023.

As a reminder, this act complements Regulation 2016/429 on transmissible animal diseases, and clarifies the following:

- Considered as a globally eradicated disease by the World Organisation for Animal Health (WOAH), **the delegated act calls for a prohibition on vaccination against rinderpest**.
- **Vaccination against Mycobacterium tuberculosis complex** (*Mycobacterium bovis, Mycobacterium tuberculosis* and *Mycobacterium caprae*)(MTBC), **is also called for to be banned**, as currently available vaccines against this complex infection do not confer full protection to vaccinated animals and compromise tuberculin skin tests or other immunological tests.
- In contrast, some Member States currently allow the regular precautionary use of vaccines against Newcastle disease, for purposes other than responding to an outbreak. In addition, there are uses of vaccines against Newcastle disease as a requirement for movements, within the Union and for entry into the Union from third countries or territories. These uses have proven to be safe and effective in preventing the disease. **Therefore, the general prohibitions and restrictions for the use of vaccines against category A diseases laid down in this regulation should not apply to such use of vaccines against Newcastle disease in those contexts.**
- Finally, certain other veterinary medicinal products, such as hyper-immune sera, antimicrobials and some immunological veterinary medicinal products may, if used for the prevention and control of certain animal diseases, mask the presence of these diseases. **Therefore, the regulation lays down certain restrictions for such veterinary medicinal products.**

Update on special control measures for African swine fever in Europe

The European Commission has updated, by an implementing regulation published on the 17th February 2023, the establishment of the special control measures for African swine fever applicable for a limited period of time by the Member States which are mentioned in the restricted zones, and listed in the Annex to Regulation 2016/429 on transmissible animal diseases.

The purpose of this text is to amend the restrictive measures according to the evolution of the current epidemiological situation of the African swine fever epizootic in Europe.

Trade in pigs and pig products from Malopolskie, Pomorskie, Łódzkie and Świętokrzyskie regions in Poland will now be allowed in certain areas without health restrictions, under the control of the competent authorities, the European Commission proposed.

In addition, new measures also subject other areas to lighter restrictions than the previous ones, such as certain areas in the regions of Lubuskie and Zachodniopomorskie in Poland.

However, some localised areas still remain subject to stricter conditions regarding the movement of pigs and pig products, including in particular localised areas of Banska Bystrica in Slovakia, as well as the Sardinia region in Italy and the Podkarpackie region in Poland.

The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed.

Publication of a surveillance plan proposal for early detection of zoonotic pathogens in ruminants by EFSA

On 17h February 2023, the European Food Safety Authority (EFSA) published a surveillance plan proposal for early detection of zoonotic pathogens in ruminants. This surveillance plan targets three diseases were in particular: **Crimean-Congo Haemorrhagic Fever (CCHF), Q-Fever and Rift Valley Fever (RVF).**

To this end, surveillance objectives have been defined as follows:

- The detection of the spread of Crimean Congo Haemorrhagic Fever (CCHF) in previously unaffected areas. Noted that, absent from most EU countries, several southern European countries have recently reported cases.
- Early and rapid detection of the spread of endemic Q fever in all EU countries, and particularly the risks in human, which remain relatively limited to date.
- The establishment of surveillance for the spread of Rift Valley Fever, aimed at reducing the risk of a possible outbreak in Europe.

Note that the specific recommendations for surveillance also take into account the epidemiology of the three diseases.

- The proposition consists of serological surveillance of domestic and wild ruminants against CCHF as well as the detection of pathogen in the collect ticks.
- For Q-Fever, *"**a baseline serological surveillance of ruminants to identify high-risk areas combined with environmental sampling"*** is recommended. In addition, *"indicator-based surveillance of abortions in ruminants is also an important component of surveillance for Q-Fever."*
- *Finally for RVF, "**indicator-based surveillance – especially of bulk milk and mosquito pathogen- is also a good option**, because the disease causes abortions and mortality in young animals" the report underlines .*

OTHER ISSUES

Latest news on animal welfare

Publication of EFSA recommendation to promote cage-free poultry farming

On 21st February 2023, the European Food Safety Authority (EFSA) published two scientific opinions on the welfare of laying hens and broilers. **The studies recommend, in particular, that these poultry should no longer be mutilated and that their feeding should no longer be restricted.** The opinions include advice on space, stocking density, lighting, dust, noise, litter and structures such as raised platforms. **The recommendations therefore encourage in their conclusions that poultry should be kept in 'cage-free systems'.**

As a reminder, the European Commission requested these scientific opinions as part of its "Farm to Fork" strategy. They will provide a scientific basis for the revision of the Animal Welfare legislation, expected in autumn 2023. It is in this framework that EFSA has been mandated to carry out this series of scientific opinions, and is organising a public online event to present its last two recommendations on 28th March 2023.

Adoption of two secondary legislation texts by the European Commission to strengthen legislation on the transport of animals by sea

On 17th February 2023, the European Commission adopted **two texts to strengthen the legislation on the transport of animals by sea**, which complements the regulation 1/2005 on the protection of animals during transport and related operations defines the responsibilities of all actors, involved in the transport chain of live animals entering or leaving the European Union.

These acts cover in particular monitoring tools, inspections and means of transport:

- The first is an implementing act detailing the practical arrangements for the registration of animals during transport by sea. **This act provides notably for the creation by the European Maritime Safety Agency (EMSA) of a common electronic database** that can be consulted by all Member States in order to facilitate checks by national authorities. The information to be entered into the database includes data on the certification of livestock vessels (expiry date of certificates, maximum surface area, type of animals that can be transported) and records of previous inspections. **The text also provides for a control to be carried out by an official veterinarian on livestock vessels on their first journey.**
- The second text is a delegated act detailing animal welfare controls during maritime transport. In particular on the inspection of ships and controls at the point of exit of ports, both for loading and unloading of animals.

In a press release on 21st February 2023, Eurogroup for Animals commented on these two new legislative texts and considers that the creation of a database is *"a toothless instrument when it comes to transports to destinations outside the European Union, of which no mention is made"*, as there is no mention of an increase in the rigour of inspections in their views. Among other things, the association calls for an official veterinarian to be present on all journey, and not just on the first trip of an approved vessel as provided for in the legislation. Finally, it deplores the fact the controls during arrival, unloading, and other transportation phases after arrival remain uncovered.

Note that **both texts have now to be published in the Official Journal of the European Union and will enter into force 20 days after their publication, expected by May 2023**.

European Commission response to parliamentary question on animal welfare legislation : increased use and reporting of animal welfare indicators should be included

On 1st March 2023, the European Commission replied to a parliamentary question written by two MEPs, Tilly METZ (Greens/EFA, Luxembourg) and Francisco GUERREIRO (Greens/EFA, Portugal) on the national implementation of EU legislation on animal welfare. As a reminder, Tilly METZ (Greens/EFA, Luxembourg) is the President of the European Parliament Intergroup on Animal Welfare, of which MEP Francisco GUERREIRO (Greens/EFA, Portugal) is also an active member.

In their question, the two MEPs highlighted the lack of effective implementation of the European legislation on animal welfare legislation in the Member States and ask the European Commission about the collection of data on national implementation of EU legislation, stressing the need to strengthen control and monitoring of this legislation. In addition, MEPs asked whether a strengthening of enforcement mechanisms and infringement procedures in the current revision of the legislation is foreseen.

Following this, the European Commission stated that one of the main findings of the evaluation of the current legislation was the lack of effective tools for monitoring and implementing the relevant measures. The

European Commission therefore explained that it intends to include in the ongoing impact assessment, policy **options to increase the use and reporting of animal welfare indicators and to make greater use of modern technology to better protect animals, including during transport and in slaughterhouses.**

Report on the European Parliament's Animal Welfare Intergroup event on cage farming and force feeding of ducks

On 16th February 2023, the European Parliament's Animal Welfare Intergroup organised an event to address the issues related to **the transition from cage farming to alternative systems in the European Union, as well as the need for a European ban on duck force-feeding.**

As a reminder, in 2021, the European Citizens' Initiative "End the Cage Age" collected almost 1,400,000 validated signatures, prompting the European Commission to work on a draft ban on cages for a range of farm animals (including chickens, pigs, calves, rabbits, ducks and geese) with a target of a phase-out by 2027.

The first part of the event was dedicated to the issues related to cage farming, with in particular the interventions of Dr Sarah ISON who presented the report *"Phasing out cages in the EU: the way to a smooth transition",* Dr Pietro PIZZAGALLI from Fumagalli Industria Alimentari SpA who came back on their award winning pig farming system, and finally, Josep BERTRAN from Urgasa group, a Spanish company producing quail in Europe, introduced its free-range farming system. The second part of the event was dedicated to force-feeding in the production of foie gras.

In conclusion, Tilly METZ (Greens/EFA, Luxembourg), Chair of the Intergroup, stressed the importance of the European Commission facilitating a sustainable transition for the benefit of animals, farmers and consumers with financial support from the EU. **She also expressed hope for an ambitious review of animal welfare legislation in October 2023.**

Event by the European Parliament's Intergroup on Animal Welfare on the actions to be taken concerning pets in the context of the war in Ukraine

The European Parliament's Intergroup on Animal Welfare is organising an online event on 8th March 2023 entitled "**Animals in Disasters: the need for protection and coordination across Europe**" held by the companion animals working group.

The event will be chaired by Petras AUSTREVICIUS (RE, Lithuania). On this occasion, Alessandro CARROTTA policy officer at the Directorate General for European Civil Protection and Humanitarian Aid Operations (DG ECHO) within the European Commission and Jackson ZEE, Head of Disaster Unit at FOUR PAWS, will be invited to participate in order to giver their opinion on this issue.