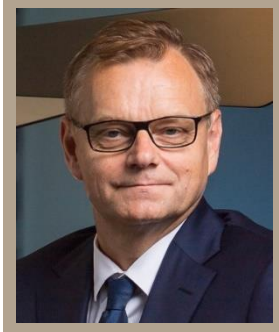
EU NEWS

December 2022

UEVP

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



This new year 2023 will be marked by several key initiatives in the animal health and welfare sector at European level. Amongst these, the publication of ***secondary legislation to complement the revision of the legislation on veterinary medicinal products*** *in force since 2019 will be important for our profession. The aim of this text will be to improve the fight against antibiotic resistance.*

The beginning of this year, which is also characterised by the Swedish Presidency of the Council of the EU from January to July, will be marked by a strong European commitment to the ***fight against antibiotic resistance****, which is a priority in Sweden's work programme.*

A second priority will be the long-awaited ***revision of the European animal welfare legislation****, which will notably include regulations on breeding conditions, transport conditions, killing conditions of animals and animal welfare labelling.*

Finally, regarding the Highly Pathogenic Avian Influenza (HPAI) pandemic in poultry, the European Food Safety Authority (EFSA) is currently ***assessing the availability of HPAI vaccines for poultry and considering possible vaccination strategies.***

I wish you all a happy new year 2023 !

Piotr KWIECIŃSKI, UEVP President

TABLE OF CONTENTS

PRIORITY ISSUES

Latest EU institutional news

Latest developments on the CAP reform

The European Commission has adopted all the National Strategic Plans (NSPs), finally approving the one of the Netherlands, which was the last to receive the green light from the European Commission on 13th December.

It should be noted that the new CAP entered into force on 1st January 2023.

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 6th to 8th December 2022.

The Committee adopted a positive opinion for a marketing authorisation application for **Brucellin Aquilon,** a new product for in vivo diagnosis of Brucella infected pigs (skin test) to discriminate false positive results by Brucella serological tests.

The Committee adopted a positive opinion for a variation requiring assessment for **Porcilis PCV ID** concerning the update of the product information to include new associated use combinations of *Porcilis PCV ID*, *Porcilis Lawsonia ID*, *Porcilis M Hyo ID ONCE* and *Porcilis PRRS*.

The Committee adopted a positive opinion for a grouped variation requiring assessment for **Simparica Trio**, concerning the addition of three new therapeutic indications: for the treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*), for the treatment of demodicosis (caused by *Demodex canis*), and for the prevention of establishment of thelaziosis (adult *Thelazia callipaeda* eyeworm infection).

The Committee adopted a positive opinion for a variation requiring assessment for **Credelio Plus**, concerning the addition of a new therapeutic indication for the treatment of demodicosis (caused by *Demodex canis*).

The Committee adopted by consensus a positive opinion for a grouped variation requiring assessment for **NexGard** and **Nexgard Spectra**, concerning the addition of two new therapeutic indications for the treatment of tick infestations with *Hyalomma marginatum* and for the treatment of ear mite infestations (caused by *Otodectes cynotis*), and to amend the product information to allow the use of the products in breeding, pregnant and lactating female dogs.

The Committee adopted a positive opinion for variation requiring assessment for **Prevomax** to align the product information application with the latest version (9.0) of the QRD template.

The Committee adopted serveral positive opinions for variation requiring assessment concerning quality-related changes for **Locatim**, **Solensia**, **Purevax RC**, **Purevax RCP FeLV**, **Purevax RCPCh FeLV**, **BTVPUR**, **Eurican Herpes 205**, **Purevax RCPCh** and **Purevax RCP** as well as **Suvaxyn CSF Marker**, **Fevaxyn Pentofel** and **Suvaxyn PRRS MLV.** It is also for **Mirataz**, **Imoxat**, **Panacur Aquasol**, **Procox** and **Bluevac BTV**.

In the context of a referral procedure from Germany concerning veterinary medicinal products containing N-methyl pyrrolidone, and in particular due to concerns relating to the appropriateness of the safety warnings for the user and the target animal, the Committee concluded that no changes need to be made in the product

information for some of the veterinary medicinal products concerned by this referral. In addition, the Committee agreed that user and/or target animal safety warnings should be added to the product information for the remaining products concerned. The Committee therefore adopted an opinion concluding that the benefit-risk balance of the products concerned remains favourable and that the marketing authorisations should be maintained or modified, as applicable.

The Committee adopted two scientific advice reports further to a request for initial advice concerning one immunological product for piglets and a substance intended for inclusion in the list of substances considered as not falling within the scope of Regulation 470/2009. Furthermore, the Committee endorsed one clarification of a scientific advice concerning a pharmaceutical product for mice, rats, hamsters, gerbils, guinea pigs, chinchillas and rabbits.

As regarding pharmacovigilance, the Committee adopted recommendations for changes to the summary of product characteristics for **Bravecto, Proteq West Nile, Procox, Zuprevo, Felpreva** and **Improvac** as outcome of signal detection activities.

Finally, The Committee adopted a report, prepared in collaboration with EFSA, on the development of a harmonised approach on exposure assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides in food of animal origin following close of public consultation.

Latest news on antimicrobial resistance at EU level

Public consultation on the draft Delegated Act by the European Commission on the prohibition of growth-promoting antibiotics in imports

The European Commission has published its draft delegated act to **ban the use of growth-promoting antibiotics in imported products of animal origin**. Initially expected by the end of January 2022, the European Commission has submitted the text for consultation until 3rd January. This text is part of the drive to implement mirror clauses.

The objective of this delegated act is to complete the 2019 legislation on veterinary medicinal products. This ban also applies to antibiotics for human use only.

This act will have to be accompanied by two other implementing acts, which will establish :

- A list of third countries whose legislation in this area is equivalent to that of the European Union, based on available evidence, such as information received on the procedures put in place to ensure the traceability and origin of the animals or products concerned.
- An official certification model for imported products, attesting to their compliance with public and animal health requirements.

After the period of input and analysis of the responses, the European Commission will submit the finalised text to the expert group composed of representatives from each Member State for voting. Once the European Commission has adopted the act, the European Parliament and the Council will have 2 months to raise any objections. If they have no objections, these new rules will only apply 24 months after the entry into force of the text establishing the model certificate.

Latest news on animal health

Publication of the Swedish Presidency of the Council of the EU work programme

Sweden will take over the Presidency of the Council of the EU at the beginning of 2023 for a period of six months, until the end of June 2023.

The main role of the rotating Council Presidency, which changes Member States every six months, is to plan and chair the meetings of the Council and its preparatory bodies, thus putting priority issues on the agenda.

Sweden, which will chair the Council for the next six months, has published its programme, which is in line with the European legislative developments planned and proposed by the European Commission. The programme presents the Swedish Council Presidency's vision for future initiatives.

In the area of animal health, and in particular with regard **to antimicrobial resistance**, the Swedish programme states that the Presidency "*will strive to maintain the possibility of effective treatment of bacterial infections in humans and animals and to keep this issue high on the international agenda*". To contribute to this, the Presidency "*will highlight efforts to ensure sustainable access to effective antimicrobials and the EU's contribution to the reduction of antimicrobial resistance at global level*".

In addition, the incoming presidency wants to "*take forward work on the **European Education Area**, for example on the **mutual recognition of qualifications***".

Publication of the latest annual report on zoonoses by EFSA and ECDC

On 13th December, the latest annual report on zoonoses, part of the "One Health" initiative, was published by the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC).

The report states that in 2021, reported cases of zoonotic diseases and food-borne outbreaks were higher overall than in the previous year, but the number of cases remained significantly lower than in pre-pandemic years. This decrease is probably related to the measures taken to control COVID-19. The few exceptions to this trend are *yersiniosis* and foodborne outbreaks of *listeriosis*, where the number of reported cases exceeds pre-pandemic levels.

To be noted that in 2021, the most common cause of foodborne outbreaks was *Salmonella,* which accounted for 19.3% of total cases. The most common sources of these salmonellosis outbreaks were eggs, egg products and "mixed foods", which are meals composed of various ingredients.

The number of outbreaks caused by *Listeria monocytogenes* was the highest ever reported. However, the increased use of whole genome sequencing techniques, which allow scientists to better detect and identify outbreaks, may explain this record level.

Campylobacteriosis remains the most frequently reported zoonosis (not necessarily linked to outbreaks) with the number of reported cases increasing (127,840, compared to 120,946 in 2020). Chicken and turkey meat was the most common source of infection. *Salmonellosis* remained the second most reported zoonotic disease, affecting 60,050 people (up from 52,702 in 2020). Other frequently reported diseases were *yersiniosis* (6,789 cases), infections caused by *shigatoxin*-producing *E. coli* (6,084 cases) and *listeriosis* (2,183 cases). The report also contains data on *Mycobacterium bovis/caprae, Brucella, Trichinella, Echinococcus, Toxoplasma gondii*, *rabies, Q fever, West Nile virus infections* and *tularemia.*

Publication of a report on the number of cases of highly pathogenic avian influenza (HPAI) in poultry and water birds

On 20th December, the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC) and the European Union Reference Laboratory jointly published a report on the number of cases of highly pathogenic avian influenza (HPAI) in poultry and water birds in Europe.

According to the report, while the number of HPAI detections in seabird breeding colonies has fallen since the previous reporting period (June to September 2022), the number of cases in water birds and poultry has increased.

The ECDC, which also contributed to the report, concluded that the risk of infection is low for the general human population in the EU/EEA, and low to medium for occupationally exposed individuals.

Following a request from the European Commission, EFSA is currently assessing the availability of HPAI vaccines for poultry and considering possible vaccination strategies. The conclusions of this work, which also involves the European Medicines Agency (EMA) and the EU Reference Laboratory, will be available in the **2nd quarter of 2023**.

Detailed information on the number of cases and their evolution is available on a new interactive dashboard published by EFSA.

Update on special control measures for African swine fever in Europe

The European Commission has updated, by an implementing regulation on 16th December 2022, 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 Sardinia (Italy) 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 Podkarpackie, Dolnośląskie, Warmińsko, Mazurskie, Wielkopolskie, Małopolskie, Świętokrzyskie and Podlaskie 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 Pomorskie, Wielkopolskie, Opolskie and Dolnośląskie in Poland, as well as the Piedmont region in Italy.

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

OTHER ISSUES

Latest news on animal welfare

12th meeting of the European Platform on Animal Welfare organised by the European Commission

On 5th and 6th December 2022, the European Commission organised its 12th meeting of the "European Platform on Animal Welfare".

The European Platform is composed of representatives from Member States and European Economic Area (EEA) countries, stakeholders and international and European organisations active in the field of animal welfare, the European Food Safety Authority (EFSA) and the European Commission, as well as representatives of the scientific community.

This platform, created by the European Commission in 2017, aims to foster an enhanced dialogue on animal welfare issues in order to develop coordinated actions on animal welfare, including commitments, dissemination of good practices and promotion of European standards in this field.

This event was dedicated to the reflections on the next revision of the animal welfare legislation, which is expected in the **3rd quarter of 2023**.

On this occasion, a representative of the European Commission's Directorate-General for Health and Food Safety (DG SANTE) gave some details on the promulgation of several delegated acts, which will set out detailed requirements for each animal species, following the revision of the European framework on farm animal welfare.

To be noted that the regulation on farm animal welfare is one of the four new regulations foreseen by the revision of the animal welfare framework. The other regulations will cover transport, killing of animals, and labelling, all of which can be based on targeted impact assessments. To date, three of the four scientific studies commissioned by the European Commission on animal slaughter, transport and product labelling have been finalised. Only the study on the breeding and keeping of animals for commercial purposes is still ongoing.

Please find the agenda of the conference and the recording of the exchanges (here, there and here).

EU Agriculture Ministers' position paper on animal welfare legislation at the last Agriculture Council

During the Agriculture Council on 11th and 12th December, EU Agriculture Ministers unanimously called for a review of EU animal welfare legislation, although with some nuances in the ambition of the reform.

Denmark, Sweden, Germany, the Netherlands, Belgium and Luxembourg were the most ambitious in their call for a review of the legislation, which was considered outdated (the last review was in 2009).

Several delegations - including France, Germany, Denmark, Sweden, Belgium - stressed the need for legislation to prevent the illegal trade in dogs and cats. France also called for an EU-wide ban on the slaughter of male chicks. Germany, for its part, cited cattle, slaughter poultry, a ban on tail docking for pigs and an end to cages among its priorities.

Several ministers, notably those from France, Spain, Italy, Portugal, Poland, Slovakia and Hungary, called for sufficiently long transition periods to give breeders and farmers time to adapt to the new rules.

Prior to the meeting, the Czech Presidency had sent delegations a note containing the conclusions of the European Commission's assessment of the EU's animal welfare directives and regulations (published on 4th October), which served as a basis for the discussions.

The Czech Presidency acknowledged that the current legislative framework "*does not fully meet the current and future needs*" of consumers and considered that the new rules should "*better reflect society's growing expectations, ethical concerns and scientific and technological developments*". But at the same time the note called for a "*gradual implementation so as not to jeopardise the economic viability of farmers*" and asked Member states to decide on this point.

Adoption of the own-initiative report on a long-term vision for the Union's rural areas by the European Parliament

The European Parliament adopted its draft own-initiative report on "A long-term vision for rural areas in the European Union - Towards stronger, more connected, resilient and prosperous rural areas by 2040" on 13th December 2022, with 465 votes in favour, 29 against and 131 abstentions.

This text - not legally binding - aims to communicate the position of the European Parliament following the publication, on 30th June 2021, of the communication on the same subject by the European Commission.

To be noted that the European Commission's communication included a rural pact aiming at committing the European, national, regional and local levels to the vision in the framework of a rural pact community launched in December 2021, as well as a rural action plan articulated around flagship initiatives, each covering different policy areas of the Union. In addition, the Communication provided for the creation of a **rural observatory** to improve analysis of rural areas and a "rural test" mechanism to assess the impact of major EU legislative initiatives on rural areas.

This own-initiative report therefore recognises the key role of rural areas, the need for specific funding for these territories and the importance of policy instruments such as local proximity actions and the rural test mechanism.

With the support of

EURALIA

info@euralia.eu