EU NEWS

December 2023

UEVP

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

The end of 2023 was marked by several key initiatives in the animal health and welfare sector at European level. These include the publication of two pieces of legislation, one on the welfare of animals during transport and the other on the welfare and traceability of dogs and cats, which will be important for our profession. They correspond to the first initiatives in the long-awaited package on the revision of EU animal welfare legislation.

Will the same approach be adopted for the other expected initiatives regarding animal breeding and killing conditions, as well as animal welfare labelling in the specific context of 2024?

Indeed, the year 2024 will be synonymous with renewal in a singular political context: the elections to the European Parliament, and more generally an institutional renewal within the European Commission and the European Council.

We will therefore have to redouble our efforts to maintain the EU priorities supported by our profession, whether in terms of animal health and welfare, and to encourage ambitious decision-making in this area.

The beginning of this year will already be characterised by the Belgian Presidency of the EU Council from January to July, will has indicated its strong commitment to the disease prevention -as part of the "One Health" initiative-, and to the fight against antimicrobial resistance, as priority in its work programme.

I wish you all a happy new year 2024 !

Volker MOSER, UEVP President

TABLE OF CONTENTS

PRIORITY ISSUES

Update on EMA activities

Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP)

The Committee for Medicinal Products for Veterinary Use (CVMP) held a meeting from 5th to 7th November 2023.

The Committee adopted positive opinion for variations requiring assessment concerning quality-related changes for **Solensia.** The committee also adopted a positive opinion for a grouped variation requiring assessment for **Frontpro** to add a new therapeutic indication for the treatment of tick infestations.

Also, the Committee adopted positive opinions for variations requiring assessment applications concerning quality-related changes for: **Arti-Cell Forte and RenuTend; Bovilis Nasalgen-C, Nobilis IB 4-91, Porcilis AR-T DF, Nobilis IB Primo QX, Nobivac DP Plus, Porcilis ColiClos, Nobivac Bb and Nobivac Myxo-RHD Plus; Broadline**; **Solensia; Tulinovet; Vectra 3D** and **Zactran.**

The Committee concluded the procedure for **Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs** (procaine benzylpenicillin), after the European Commission requested clarification on a modification requiring assessment, for environmental safety reasons.

The Committee adopted a questionnaire to stakeholders to follow up with a recommendations made in the reflection paper on dose review and adjustment of established veterinary antibiotics, and possible modifications to dosage regimens.

After a public consultation, the Committee adopted a revised guideline on the conduct of pharmacokinetic studies in target animal species, to take account of scientific developments in the field in recent years and animal welfare considerations.

After a public consultation, the Committee adopted a revised guidelines on the calculation of dose factor to be submitted to the Union Product Database. This guideline has been developed to provide specific guidance on the considerations and calculations related to the dose factor which (alongside the submission of the yearly sales data) will allow the calculation and publication of the yearly reported incidences of adverse reactions for each veterinary medicinal product.

The Committee adopted a revision to the guideline on the evaluation of the benefit-risk balance of veterinary medicinal products (following a 6-month period of public consultation) in order to update and align it with the regulatory and scientific framework provided by Regulation (EU) 2019/6, as well as to take account of experience gained in the evaluation of veterinary medicinal products before and after marketing authorisation.

The Committee adopted its work plan for 2024, which covers the evaluation of activities for veterinary medicinal products (including pharmacovigilance, scientific advice and marketing authorisations) as well as more varied horizontal activities such as the fight against antimicrobial resistance.

Finally, The Committee approved a revised guidance document on Quick Response (QR) codes in the product information of veterinary medicinal products. The guidance is applicable to the labelling and/or package leaflet of veterinary medicinal products authorised via centralised, decentralised and national procedures. This update has no impact on already submitted or approved QR codes requests.

Latest news on animal health at EU level

Publication of the quarterly and annual EFSA reports on the evolution of avian influenza, as well as two implementing decisions concerning new outbreaks of avian influenza in Europe

On 14th December, the European Food Safety Authority (EFSA) published its **quarterly and annual reports on the evolution of avian influenza.**

The quarterly report (covering the period from September to December 2023) indicates that in recent weeks there has been an increase in the detection of the avian influenza virus in wild birds in Europe. It is interesting to note that this increase began later than in previous years, which could be due to a delay in the autumn migration of several species of waterfowl.

The annual report brings together, analyses and summarises the data from surveillance activities over the past year and reports on the results for 2022. According to the report, seropositive poultry establishments were found in 4 reporting countries (Belgium, Poland, Spain and Sweden) and, as in previous years, the highest percentages of seropositive poultry establishments were found in poultry establishments rearing breeding geese. With regard to virological investigations: 54 poultry farms reported the presence of virus A (H5NA), 17 of virus H (H5N8), 2 of virus A (H5N1) of unknown pathogenicity and 1 of low pathogenic avian influenza (LPAI) (H5N3). In addition, reporting countries also reported 984 wild birds positive for low pathogenic avian influenza (LPAI).

EFSA has also launched a call for tender to establish active surveillance capacities for highly pathogenic avian influenza in wild birds in Europe, until 21st February 2024.

In parallel, on 7th December and 20th December, the European Commission published two implementing decisions concerning new regions affected by avian influenza. The affected regions, placed under protection and surveillance zones, are as follows:

- **Bulgaria**, in the region of Dobrich
- **Denmark**, in the Holbæk municipality
- **Italy**, in the province of Verona
- **Hungary (and Roumania in neighbouring regions)**, in the counties of Bács-Kiskun, Békés, Csongrád-Csanád, Hajdú-Bihar, Jász-Nagykun-Szolnok, Szabolcs-Szatmár-Bereg and Komárom-Esztergom
- **The Netherlands**, in the provinces of Gelderland and Zuid-Holland
- **France**, in the departments of Morbihan and Somme
- **Belgium**, in the province of West Flanders
- **Germany**, in the regions of Brandenburg, Lower Saxony, Schleswig-Holstein, Mecklenburg-Vorpommern and North Rhine-Westphalia
- **Poland**, in the region of West Pomeranian Voivodeship

Publication of a communication by the European Union and adoption by the European commission of an implementing regulation laying down special measures to tackle African swine fever

On 18th December 2023, the European Commission published a communication on **guidelines for the prevention, control and eradication of African swine fever in the European Union**.

As a reminder, a communication is not legally binding. It is mainly a means for the European Commission to share its interpretation, guidance or analysis on issues related to specific European policies.

The purpose of these guidelines on African swine fever (ASF) is "*to provide guidance to Member States and/or stakeholders on the tools available for the prevention, control and eradication of ASF in response to the epidemiological situation of this disease in the EU and worldwide*".

The document sets out several recommendations on additional measures to be adopted to better implement swine fever prevention, control and eradication measures in wild boar and farmed pigs. These measures include notably "*regular visits by official veterinarians*", which could be organised in establishments where farmed pigs are intended for consumption.

Following this, the European Commission published an implementing decision establishing special control measures for African swine fever on 19th December 2023.

This decision establishes new surveillance and protection zones in certain EU countries:

- **Poland**, in the Pomorskie Region
- **Slovakia**, in the Nitrianský and Turčianske Teplice Regions
- **Latvia**, in the counties of in the Gulbenes, Madonas, Jēkabpils, and Rēzeknes
- **Italia**, in the regions of Piedmont, Liguria and Lombardy
- **Croatia**, in the counties of Brodsko-Posavska, Vukovarsko Srijemska, Osijek-Baranja and the region of Zadarska

Publication of an implementing decision by the Commission concerning certain interim emergency measures relating to sheep pox and goat pox in Greece

On 18th December 2023, the European commission published an implementing decision on provisional emergency measures relating to sheep pox and goat pox.

Sheep pox and goat pox are infectious viral diseases affecting sheep and goats which can have a serious impact on the animal population concerned and on the profitability of farms, disrupting the movement of these animals and the products derived from them within the EU and exports to third countries.

This implementing decision concerns Greece and Bulgaria. Both countries have been affected by the disease in some of their regions. Greece has two regions in the protection and surveillance zone: **the regional unit of Phthiotis**, in the region of Central Greece and **the island of Lesvos**, which continues to be affected by the disease. In Bulgaria it's the **province of Burgas** that is under protection and surveillance.

This execution decision applies until 15th April 2024.

Launch of a public consultation by the European Commission on a draft delegated act concerning the rules for oral administration of veterinary medicinal products

The European Commission has opened for contributions, until 10 January 2024, a **draft delegated act** concerning **rules applicable to veterinarians and animal keepers in the case of oral administration of veterinary medicinal products mixed with water, milk or animal feed.**

These rules are intended to contribute to the safe and effective use of veterinary medicinal products, to public and animal health and to the safety of the food chain and the environment.

The draft delegated act covers in particular:

- The treatment decision;
- The simultaneous use of veterinary medicinal products and other categories of products;
- Information and instructions on disposal;
- The prescription of antimicrobial and antiparasitic veterinary medicinal products;
- Handling and use of veterinary medicinal products by animal keepers;
- Equipment;
- Product information and, finally, guidelines on good practice.

Although the European Commission initially planned to adopt this text in the **4th quarter of 2023**, it is more likely that it will be presented in the **1st quarter of 2024**. Once adopted, the regulation will come into force on the 20th day following that of its publication in the Official Journal of the European Union, with application 18 months after the date of entry into force of the text.

OTHER ISSUES

Latest news on animal welfare at EU level

Publication by the European Commission of two legislative proposals on animal welfare during transport and on the welfare and traceability of dogs and cats

- **The first proposal for a regulation concerns the welfare of animals during transport** (including a Question & Answers document, a fact sheet and the study), and aims mainly to limit journey times and regulate animal transport conditions. This proposal is part of the legislative package on animal welfare promised by the European Commission (among the other proposals expected from the Commission, the missing proposals are those on animal welfare during breading, at killing/slaughter and on animal welfare labelling).
- **The second proposed regulation concerns the welfare of dogs and cats and their traceability** (Q&A and fact sheet). This legislation, directly applicable in all Member States, covers only dogs and cats (and not the broader category of pets) kept by breeders, dealers, pet shops and shelters, with a view to creating a more level playing field between operators.

Concerning legislation on animal welfare during transport:

Unsurprisingly, the European Commission **did not include a provision to ban live animal exports to third countries**. This measure, strongly supported by the Intergroup's MEPs and animal welfare organizations, had been deemed to have "*very negative consequences for the EU economy*" following publication of the impact study in April 2023, and had also been the subject of criticism in the Council, from eight member states.

The text also includes details of the role expected of veterinarians:

Injured or sick animals, or those with physiological weaknesses or pathological processes, may be considered fit for transport under the following conditions:

- They must be **transported under veterinary supervision for or following veterinary treatment or diagnosis**, without the animals concerned suffering unnecessary pain or mistreatment;
- Animals which have undergone veterinary surgical procedures are fit for transport, provided that wounds do not bleed and that measures are taken to minimize physical contact with the wound;
- Slightly injured or sick animals, whose transport would not cause additional suffering, are fit for transport**; in case of doubt, veterinary advice should be sought**;
- If an animal becomes ill or injured during transport, it must be separated from the rest of the animals and **receive the necessary veterinary care as quickly as possible**;
- **Sedatives may only be administered under veterinary supervision**;
- Cats and dogs must receive the **necessary preventive veterinary treatment** before transport;
- In the case of aquatic animals showing abnormal clinical signs, they must be slaughtered with prior stunning or isolated and examined by a veterinarian.

Veterinarians are also required to be present during transport:

- A veterinarian must carry out **official controls on board the livestock transport vessel throughout the first voyage, after approval and before renewal of this approval**;
- **Loading and unloading** of animals must be supervised by a veterinarian.

Concerning legislation on the welfare and traceability of dogs and cats:

The text sets out a number of rules and practices designed to guarantee the well-being of dogs and cats, in particular via the following provisions:

- **Control of breeding rules**: frequency limits and minimum age.
- **A ban on practices considered painful**: such as otectomy (ear cropping) and caudectomy (tail docking) - unless carried out for veterinary reasons and under anaesthetic.
- **The obligation for animal handlers to acquire a minimum level of competence, and the responsibility of member states to ensure that training courses are offered**: Veterinary advisory visits will be organized in establishments, and training will have to be provided for anyone caring for dogs and cats in breeding establishments, pet shops or shelters.
- Finally, **awareness-raising measures**: dog and cat suppliers will have to ensure that potential future owners are made aware of the importance of responsible ownership, i.e. the need to provide their pets with adequate care, nutrition and medical monitoring.

Furthermore, with regard to identification and registration measures, the regulation states that **all dogs and cats will have to be microchipped and registered in a national database before they can be supplied at EU level. In addition, member states' databases will have to be interoperable**. According to the European Commission, this "**enhanced traceability**" should enable better monitoring and control of animal breeding, trade and movements by the authorities on the one hand, and more reliable information for citizens when purchasing a pet on the other. Thus, 3 years after the regulation comes into force, the implantation of a subcutaneous transponder containing an electronic microchip **will have to be carried out by a veterinarian or under the responsibility of a veterinarian** (no later than 3 months after the animal's birth). Proof of this act will be provided for each dog or cat by the seller to the purchaser.

Next steps for both legislations:

- Legislative work can now begin in the European Parliament and Council. Member States and MEPs will have to define their respective positions. The European Parliament will appoint a rapporteur and shadow rapporteurs to work on the text.
- There is still the issue of the calendar: the aim will be to make rapid progress on the text ahead of the European elections (scheduled for June 2024). However, it seems unlikely that the text will be adopted before then.

In the Council, the majority of member states welcomed the legislative proposals, with the exception of Denmark, the Netherlands and Luxembourg, who called on the European Commission to be more ambitious in limiting animal transport times**.** France, for its part, welcomed the maintenance of the possibility of exporting live animals to third countries, as well as the development of mirror clauses.

These legislative proposals received a mixed reception from a number of stakeholders, who expressed their position, including Eurogroup for Animals, Animal Health, Copa Cogeca and Four Paws.

Finally, the European Commission has opened its proposal for a regulation on animal transport to consultation, inviting stakeholders to give their opinions until 4th February 2024.

Publication Feedback from the 14th Conference of the EU platform on Animal Welfare

On 7th December, the 14th conference of the EU Platform on Animal Welfare took place. This platform, which organises biannual conferences on key issues related to animal health and welfare, is made up of representatives of Member States and countries of the European Economic Area (EEA), 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.

As a reminder, this platform was created by the European Commission in 2017 to foster an enhanced dialogue **on animal welfare issues in order to develop coordinated actions on animal welfare, whether in terms of commitments, dissemination of good practices and promotion of European standards in this area**.

Numerous points were discussed at this 14th edition (agenda), including:

- The presentation of the EFSA report on scientific and technical assistance on welfare aspects related to housing and health of cats and dogs in commercial breeding establishments;
- A presentation of the European Commission's Communication on the European Citizens' Initiative "Fur Free Europe";
- The place of animal welfare indicators in relation to different policy instruments (e.g. CAP) and the possibility of creating a sub-group of specialised experts within the European Commission;
- A presentation of the report on "Extreme livestock farming: mapping legislation in Europe".

On this occasion, the European Commission also presented its two proposals for legislation on the welfare of animals during transport and the regulation on the welfare of dogs and cats, as well as a report on EU implementing measures concerning the illegal trade in cats and dogs.

Publication of the Belgian Presidency's work program for the first half of 2024

On 7th December 2023, the future Belgian Presidency of the Council published its work program and priorities for 2024. The Belgian Presidency of the Council will run from 1st January 2024 to 30th June 2024.

The Belgian Presidency has established 6 "strategic priorities" for its term of office:

- Defending the rule of law, democracy and the unity of the Union;
- Strengthening competitiveness;
- Pursuing the green and fair transition to a low-carbon economy;
- Strengthening the EU's social and health agenda;
- Protecting people and borders;
- Promoting a global Europe.

Among the main issues that could have an impact on the field of animal health and welfare, the Presidency has indicated that it would like to:

- Give priority to animal health and disease prevention as part of the "One Health" initiative, including the following 3 aspects:
  - **Vaccination**: with the deployment of vaccines against epizootic diseases and other high-impact animal diseases. To this end, the Belgian Presidency plans to organise a conference on the deployment of vaccination (on 24th January 2024) and a conference on antimicrobial resistance (on 7th May 2024).
  - **Biosecurity**
  - And pay attention to "**shortages in the veterinary profession**".
- Push ahead with the ongoing work on **animal welfare legislation**, including the proposed regulation on the welfare of animals during transport and the proposed regulation on the welfare and traceability of dogs and cats.

Publication of a draft delegated directive by the European Commission on the Animals used for scientific purposes

On 4th January, the European Commission opened for consultation, until 1st February, a draft delegated directive on the welfare of animals used for scientific purposes, and more specifically to adapt standards of care, housing and killing.

The purpose of this delegated act is to adapt two annexes to the Directive on the protection of animals used for scientific purposes. The changes will apply to species currently not covered by the annexes but falling within the scope of the Directive.

Launch of an enquiry by the European Ombudsman into the European Commission's lack of response to the 'End the Cage Age' citizens' initiative

On 20th December, the European Ombudsman opened an investigation into the European Initiative lack of response to the European citizens 'initiative (ECI) "End the Cage Age", focusing in particular on the insufficient transparency of the EU decision-making process.

In a press release published on 3rd January, the Ombudsman said that it had received many complaints about the European Commission's handling of the ECI and the absence of a new timetable for the draft review of animal welfare at farm level, which was part of the review package on animal welfare promised by the European Commission.

As a reminder, although the initiatives put forward as part of the European Citizens' Initiative (ECI) are note binding on the European Commission, it nonetheless emphasised its intention to consider them as part of the review of animal welfare legislation, which was due to be published in the fourth quarter of 2023. Nevertheless, the European Commission has only made public two initiatives of the announced proposals (which do not include this provision), without specifying a possible new timetable for the missing proposals.

The Commission has until 31st January to answer this investigation.