EU NEWS

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UEVP

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

This month we would like to congratulate the newly elected Members of the European Parliament. UEVP is looking forward to work closely with the new MEPs during the next five years on important subjects for our profession such as the implementation of the fight against antibiotic resistance or the upcoming revision of the EU animal welfare strategy which has been listed as a top priority for the futures by EU citizens in a survey launched by the European Commission. We will keep following the nominations within the European institutions during the upcoming weeks.

Thierry Chambon, UEVP President

TABLE OF CONTENTS

PRIORITY ISSUES

Organisations reacted to the draft delegated act on identification and registration of pets

The stakeholders consultation on the draft delegated regulation regarding the rules on establishments keeping terrestrial animals, traceability of certain terrestrial animals and their identification and registration was closed on 22 May 2019. As a reminder, this text comes from Regulation 2016/429 known as "Animal Health Law" (AHL), and **does not provide new provisions regarding identification of dogs, cats and ferrets** at European level.

The consultation gathered in total **64 contributions** from different professional organisations, national authorities and NGOs. Among these contributions, **several regret the lack of ambition on pet identification**, and were expecting the possibility to create interoperable electronic databases in the European Union:

- FOUR PAWS considers that the provisions laid down in articles 109 and 118 of the AHL were not fully used and **recommends stronger provisions regarding cross-border traceability of pets**, with exchange of information between Member States.
- The NGO Eurogroup for animals is **disappointed about the small progress brought by the delegated act regarding pet traceability**. The AHL could have allowed the European Commission to impose minimal provisions regarding identification of individual animals and common rules on the exchange of information between electronic databases.
- The Federation of Veterinarians of Europe (FVE) argues that mandatory identification and registration of dogs across Europe are essential for the control of dog population. **Interoperable devices could limit the risk of fraud** (especially illegal puppy and kitten trade) and the entry of certain animal diseases on the European soil**. A robust identification, a registration system and reinforced controls would be crucial** for animal health, animal welfare, public health and consumer protection.

The European Commission will now adopt the delegated act. It can take into account the public observations and modify the draft act accordingly. After its adoption, the European Parliament and the Council of the European Union will have two months to raise objections if needed. Otherwise, the delegated act will enter into force.

The European Commission launches a new version of the Union register of pharmaceuticals

On 3 May 2019, the European Commission launched a new version of its Union Register of medicinal products. Available since 1995, the Union Register lists **all medicinal products for human and veterinary use** (over 1.300 medicines) authorised by the Commission through the centralised procedure. It also covers designation of orphan medicinal products, refused authorisations and reviews related to nationally authorised medicinal products. This update provides a **whole range of additional features**, including filtering and export functionalities, and aims at offering an improved experience for all users through simplified navigation and greater compatibility with mobile devices.

The EFSA reports high rates of compliance on veterinary medicine residues

The European Food Safety Agency (EFSA) published a report on 13 May 2019 about the monitoring of veterinary medicinal product residues in live animals and animal products. It summarises the monitoring data collected in 2017 on over 700,000 samples collected by all Member States. The data shows **high rates of compliance with**

recommended safety levels: the percentage of samples that exceeded maximum levels was **0.35% for the year 2017**. This figure is within the **range of 0.25%-0.37% reported over the previous 10 years**. As it is the first time EFSA collected these data from Member States (the information was previously submitted to the European Commission), it will allow the Agency to make comparison with other areas such as food additives, chemical contaminants, pesticides residues and antimicrobial resistance across years. It will **enable better analysis of the risks to human and animal health.**

Eurogroup for animals is optimistic regarding the potential of the new EP in defending animals' voice

The NGO Eurogroup for Animals has published on 27 May its first analysis of the European elections, and the composition of the newly-elected European Parliament. They welcome the fact that **more than 100 candidates who pledged to act for animals by signing their pledge #VOTE4ANIMALS have been elected as MEPs**, with representation across the political groups and across the EU. In order to make change happen for animal welfare, the NGO **encourages new MEPs to join the EP Intergroup on the Welfare and Conservation of Animals**, which have frequently led to concrete improvements in EU animal welfare-related policy making.

Update on the 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 21-22 May 2019, and re-elected David Murphy from Ireland as its Chair for another three-year mandate. It adopted by consensus positive opinions for initial marketing authorisation application for **EVICTO** and **NASYM**. The Committee adopted by consensus positive opinions for type II variation applications for **Bravecto Plus, CLYNAV, Clomicalm, CYTOPOINT, Inglevac CircoFLEX, Melovem and Porcilis PCV M Hyo**. The CVMP adopted by consensus positive opinions for type IB variation application for **MiPet Easecto**, **Stronghold Plus**, **Simparica** and **Fevaxyn Pentofel**. The Committee also adopted one scientific advice report further to a request for initial advice on safety issues for a new pharmaceutical veterinary medicinal product for musculoskeletal disorder indications in dogs.

Publication of the EMA Annual Report 2018

The Agency published its 2018 Annual Report during this month. Approved by the EMA Management Board in March, the document presents the key achievements in 2018, especially **the preparation for Brexit and the Agency's relocation to Amsterdam**. The part titled 'contributing to animal health' relates the Agency's efforts to **encourage a more ethical use of animals in medicine testing, decrease the sales of veterinary medicines** and the publication of new guidance on maximum residue limits.

EMA facilitates early engagement with medicine developers to combat antimicrobial resistance

On 24 May 2019, the EMA has opened up the early dialogue through its Innovation Task Force (ITF) **to all medicine developers who work on therapeutic approaches** for the treatment or prevention of bacterial and fungal infections. ITF is a forum for dialogue between regulators and developers of innovative emerging therapies, methods and technologies, in the early stages of research and development. ITF is usually reserved for innovative medicines. Given **the growing threat to public health caused by antimicrobial resistance** and the

need for new treatments, EMA is inviting all developers working on medicines for the treatment or prevention of life-threatening microbial infections to enter into early dialogue with the Agency to help strengthen the drug development pipeline for new antimicrobials.

This platform for early dialogue will ultimately contribute to **prioritising and speeding up the development of antimicrobial medicines**, which is in line with the European Parliament Resolution September 2018 on "A European One Health Action Plan against Antimicrobial Resistance".

OTHER ISSUES

Latest news on animal disease at EU level

- **African Swine Fever (ASF):** Several outbreaks have been identified during the month in Hungary and Poland. The European Commission amended two times (on 16 and 27 May) its implementing decision to establish new high-risk areas in the affected regions and implement sanitary measures accordingly.

Latest updates on animal welfare at EU level

A public consultation recognises animal welfare as a top EU priority for the future

Ahead of the informal European Council of Sibiu, Romania on 9 May 2019, the European Commission published a report of the first EU-wide citizen's consultation on future priorities of the EU. **1 out of 7 citizens mentioned animal welfare in an open question about their hopes for the future EU priorities**. 13% of citizens also said that decisions taken at EU level for the welfare of animals would make them prouder to be European. Eurogroup for Animals welcomes these findings, as it is a concrete record that **citizens rank animal welfare almost as highly as taxation and combating climate change** when asked what they think should be the priorities for the future.

The European Commission starts its preparatory work for the evaluation of the EU animal welfare strategy

On 17 May 2019, the European Commission opened a stakeholder consultation on the roadmap of the **evaluation of the EU animal welfare strategy**. The 2012-15 EU Strategy for Protection and Welfare of Animals aimed to **improve animal welfare standards and ensure they are applied and enforced**, and was completed in March 2018. The need for an evaluation was expressed in a recommendation made by the European court of Auditors in a Special Audit Report published last year. The future evaluation, planned for the last quarter of 2019, will **assess the EU Strategy's overall effectiveness, relevance, coherence and EU added value**, including with other EU policies.

The consultation for the roadmap is open until 16 June 2019. It is possible to submit comments and suggestions here.

Publication of a study about the use of alternative methods in research

In the framework of a University Open Day held in Milan, a report on the **use of alternative methods in research** has been published on 6 May 2019. The purpose of the initiative is to equip future researchers, regulators and decision makers with the necessary understanding of alternative approaches to enable them to address research and testing needs with modern tools and techniques. The overall aim is to **accelerate the uptake of the Three Rs** (reduction, refinement and replacement) and to reduce the reliance on animal testing. During the open Day, **examples or reduction, integrated testing strategies, and innovative in vitro assays** in the context of environmental monitoring were given by the speakers from academia and industry.

The European Commission approves a ECI to protect the bees and other insects in Europe

On 15 May 2019, the European Commission decided to register a European Citizens' Initiative (ECI) entitled 'Save the bees! Protection of biodiversity and improvement of habitats for insects in Europe'. The organisers call on the Commission to 'adopt legislation to maintain and improve habitats for insects as indicators of an undamaged environment'. The initiative focuses on the creation of mandatory targets to make the promotion of biodiversity an overall objective of the Common Agricultural Policy (CAP), such as **dramatically cut the use of pesticides, ban harmful pesticides or effectively establish conservation areas.**

The registration of this initiative took place on 27 May, starting a one-year process of collection of signatures of support by its organisers. Should the initiative receive one million statements of support within 1 year, from at least 7 different Member States, the Commission will have to react within 3 months. The Commission can decide either to follow the request or not, and in both instances would be required to explain its reasoning.

Some Member States asked clarification of the legislation about new GMOs

During the Agriculture Council on 14 May 2019, several ministers asked the European Commission to clarify the provisions of the GMO Directive in order to take into account **plants bred from new techniques of mutagenesis**. In a ruling in July 2018, the Court of Justice of the European Union ruled that **organisms obtained from mutagenesis, in particular the 'new breeding techniques' are GMOs under the scope of the Directive**. If the Agriculture Commissioner, Phil Hogan, said that the Commission would not adopt any proposition regarding the issue during this mandate, some countries (France, Germany, Belgium, Slovenia, Spain, Italy, Finland, United Kingdom etc.) asked the Commission to take an initiative in the view adopting new rules.

Opening of a consultation on trade restriction on certain species of wildlife

On 23 May 2019, the European Commission opened a stakeholder consultation on a draft implementing regulation (+ annex) on **rules restricting trade for certain species of wild plants and animals**. The purpose of the initiative is to limit wildlife trafficking from particular third countries, that can be traded as live animals or hunting trophies for example. The draft act updates the currently applicable list established in October 2017. The consultation is open until 20 June. It is possible to give a feedback via this link.