# **EU NEWS**

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In October, the audition process of the newly appointed European Commissioners will begin within the European Parliament. Pending of the European Parliament's approval of the entire composition of the Commissioners' college, the new Commission will begin its work on November 1<sup>st</sup>. The fight for animal health and animal welfare has been clearly detailed as a priority by Ursula von der Leyen, the President of the European Commission in the mission letter she sent to Stella Kyriakides, the designated European Commissioner for health along with the launch of an Action Plan to fight antibiotic resistance. The UEVP welcomes all these initiatives and will be glad to participate in their implementation alongside the European institutions.

# Piotr KWIECIŃSKI, UEVP President

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# PRIORITY ISSUES

# Ursula von der Leyen presents the future European Commissioners and their portfolio

On **10 September 2019**, the elected President of the European Commission, Ursula von der Leyen held a press conference to announce the nomination of the new European Commissioners and the details of their portfolios. As a reminder, each Member State nominated one candidate for the office of European Commissioner. These candidates will officially take office - after being approved by the European Parliament - on 1 November 2019 (The Members of the European Parliament can approve or reject the composition of the entire Commissioners' college, not each Commissioner individually). For the first time, parity will almost be achieved with a European Commission composed of 13 women and 14 men.

**Stella Kyriakides**, the **Cyprian Commissioner**, **will be in charge of Health** within the von der Leyen Commission. She worked for the Ministry of Health in her country for years before being elected as a member of the Cyprian Parliament and becoming the President of the Parliamentary assembly of the Council of Europe in 2017.

As Commissioner in charge of Health, she will have authority over the Directorate General "Health and Food Safety" (DG SANTE). In her <u>mission letter</u>, Ursula von der Leyen, indicates various priorities that might have a significant interest for veterinarians such as:

- The implementation of an **Action Plan against Antimicrobial resistance** with the goal to reduce the antibiotics consumption of 25% within the European Union in 2030;
- The promotion of Animal welfare;
- The fight against animal disease;
- The implementation of the "Farm to fork strategy" with the aim to improve the sustainability of the food chain from production to consumption.

Furthermore, Janusz Wojciechowski, the Polish Commissioner, will be in charge of Agriculture. In its <u>mission</u> <u>letter</u>, Ursula von der Leyen indicates that he will be in charge of the simplification and the modernization of the Common Agricultural Policy. He will also work on the sustainability of the food production system within the European Union.

Both of these Commissioners will work under the authority of **Frans Timmermans**, executive Vice-president in charge of the European Green deal.

## Next steps:

- Until 8 October 2019: auditions of the future Commissioners within the European Parliament
- **21-24 October 2019:** Plenary session of the European Parliament during which the approval vote of the next European Commission will take place.

## Internal Market Services: Commissioner Designate Sylvie Goulard in the continuity of its predecessors.

Before her hearing in front of MEPs sitting on the Internal Market and Consumer Protection Committee (IMCO), Sylvie Goulard, like the other Commissioners-designate, had to take part in a written question and answer exercise in order to outline the action she intends to take during her mandate.

On the particular question of the Internal Market for Services, if she considers that it represents a great potential for the European economy, she does not foresee a legislative revolution, but is rather a continuation of her predecessors. Her action will include:

- Ensuring the proper functioning of existing legal tools, including the Services Directive and the
  Professional Qualifications Recognition Directive, for which she expects a better commitment from the
  Member States with which she intends to develop "partnerships" without specifying what it means.
  On the specific question of professional qualifications, she wishes to facilitate recognition, particularly
  through the generalization of the European professional card, beyond the professions already covered
  at this stage by this tool;
- Ensuring that the Directive on proportionality control is transposed as quickly and as ambitiously as
  possible into national law by the Member States. Here again, she plans to set up "Commission Member States" partnerships in order to facilitate their implementation.

During her hearing before the IMCO committee of the European Parliament, Sylvie Goulard did not address in depth the questions related to the internal market services. On the contrary, she did not seem in her "comfort zone" while addressing these dossiers, for which no important changes are expected, at least for the beginning of her mandate.

# Latest news on antimicrobial resistance at EU level

Open letter to Members of the European Parliament on antimicrobial resistance

On September 12, 17 organisations active in human and animal health have sent an <u>open letter</u> to the Members of the European Parliament (MEPs), urging them to bring antimicrobial resistance (AMR) to the forefront of EU interinstitutional discussions and to support the establishment of a dedicated AMR parliamentary group.

The signatories insist on the fact that EU measures should reflect the priorities laid down in the Commission's One Health Action Plan against AMR. They also call on the European Parliament to bring AMR and the importance of the One Health approach to the forefront of EU interinstitutional discussions by bringing this topic up during the hearings of the Commissioners-designate and by supporting the establishment of a dedicated, holistic AMR parliamentary group in the form of an inter-group or an interest group, in partnership with civil society and stakeholders.

As a reminder, a parliamentary inter-group is an unofficial grouping of MEPs who are interested in a particular topic which does not necessarily fall within the scope of the European Parliament's normal work but may be of interest to wider society. Intergroups hold informal discussions and promote exchanges between MEPs and civil society.

Latest update on the delegated regulation on the rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs

# The European Parliament requested an extension of the review period on the delegated act concerning the identification and registration of terrestrial animals

On 4 September 2019, the European Commission accepted the European Parliament's request to add two months to the observation period during which the Parliament and the Council may comment on the publication of the delegated act completing Regulation 2016 / 429 with regard to the rules governing establishments holding terrestrial animals and hatcheries as well as the traceability of certain kept terrestrial animals and hatching eggs. Thus, the two institutions have until 4 November 2019 to make observations. This extension request can easily be explained by the fact that the new European Parliament did not really begin its work until 2 September 2019. This extension also gives MEPs the possibility to make their voices heard on the subject.

As a reminder, this <u>delegated regulation</u> (+ <u>annex</u>) concerning the rules relating to establishments holding terrestrial animals and the traceability of certain kept terrestrial animals advocates the status quo as regards to the identification and registration of pets.

Nevertheless, the explanatory memorandum reports the main reactions and contributions of the stakeholders to this text. It shows in particular that "a number of requests for the introduction of rules relating to the traceability of pet animals have been formulated." The European Commission states that "these rules on traceability should be adopted on the basis of the delegated and implementing powers conferred on the Commission in Part VI of the Animal Health Law Regulation", i.e. the part concerning the non-commercial pets. Thus, the European Commission seems to leave the door open for future provisions concerning the identification and registration of pets, especially during non-commercial movements.

The main provisions of the delegated act concerning cats, dogs and ferrets can be found in these articles:

- Articles 3 and 9: Registration requirement for carriers and host institutions (kennels, shelters);
- Article 70: Identification of cats, dogs and ferrets by injectable transponders;
- Article 71: Identification document when a transfer to another Member State occurs (corresponds to the European passport);
- Article 72: previous rules apply to any other kinds of movements than the non-commercial ones.

# Debates over articles 45 and 46 of the delegated act concerning the identification and registration of terrestrial animals

A great deal of discussions took place over articles 45 and 46 of the <u>delegated act</u> concerning the identification and registration of terrestrial animals. These two articles provide for the rules concerning the means and methods of identification of ovine and caprine animals.

The main point of disagreement concerns the obligation of electronic identification for ovine and caprine animals of less than 12 months old destined for slaughter after undergoing an assembly operation or after undergoing a fattening operation in another establishment. Some stakeholders assess that this kind of obligation would put too much financial burden on breeders as the price of an electronic identification device costs nearly as much as the animal itself. Others state that these means of identification are considerably bigger than the non-electronic ones and will thus be problematic from the point of view of the welfare of small animals.

French farmer organisation 'Confédération paysanne' called, on august 7, on the French Agriculture Ministry about these articles and numerous Members of the European Parliament also underlined this issue in a discussion with the European Commission that took place during the Agricultural Committee of the European Parliament of September 25.

# The European Commission presented a Delegated Regulation relative to the rules on specific official controls on consignments of certain animals and goods originating from, and returning to the Union following a refusal of entry by a third country

In the context of <u>Regulation (EU) 2017/625</u> on Official Controls (OCR) establishing the framework for official controls and other official activities to verify the correct application of Union agri-food chain legislation, the European Commission published, on September 23<sup>rd</sup>, a <u>delegated regulation</u> supplementing the above mentioned regulation as regards rules on specific official controls on consignments of certain animals and goods originating from, and returning to the Union following a refusal of entry by a third country.

This delegated act has not yet entered into force. It is subject, for two months since September 23<sup>rd</sup>, to the right of the European Parliament and the Council to object, in accordance with Article 290 (2) of the Treaty on the Functioning of the European Union.

# The European Commission released two informative documents about regulatory guidelines for medicinal products for veterinary use.

In the context of the Union veterinary pharmaceutical legislation, the European Commission released, in August, a <u>document</u> meant to help readers understand the legislation around marketing authorisation of veterinary medicinal product. In the same context, another <u>document</u> was released by the European Commission informing the reader about the guideline on the packaging information of veterinary medicinal products authorised by the European Union.

These documents are part of the <u>sixth volume of EudraLex</u> entitled : "Notice to applicants and regulatory guidelines for medicinal products for veterinary use".

## 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 10 to 12 September 2019. It adopted by majority a positive opinion for an initial marketing authorisation application for Gumbohatch. Furthermore, the Committee adopted by consensus a positive opinion for an initial marketing authorisation application for Nobivac Myxo RHD Plus. It also adopted by consensus positive opinions for the following type II variation applications for Bravecto, Posatex and Rhiniseng, Quadrisol and Vectra Felis. Finally, it adopted by consensus a negative opinion for a type II variation application for Velactis.

Concerning renewals of marketing authorisation, the Committee adopted by consensus positive opinions for the renewal of the marketing authorisations for Bovela, Nexgard Spectra and Suvaxyn CSF Marker.

About community referrals and related procedures, the Committee started a procedure for Ronaxan and its associated names (doxycycline hyclate) and a procedure for Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection, and associated names, and generic products thereof (dinoprost tromethamine).

In addition, the Committee adopted two scientific advice reports further to requests for:

- Initial advice on quality and efficacy issues for a new immunological veterinary medicinal product for horses:
- Initial advice on quality issues for a new veterinary medicinal product for a dermatological indication in dogs.

Following the Committee's review of five requests for classification under the MUMS/limited marketpolicy, the CVMP classified:

- A product (antineoplastic agent) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable.
- A product (sensory organ indication) for dogs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable.
- A product (dermatological) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable.
- A product (immunological product) for horses as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable.
- A product (immunological) for pigs as indicated for MUMS/limited market and eligible for reduced data requirements, where applicable.

The three firsts products are not eligible for financial incentive, the two last ones are.

The Committee reviewed the PSURs for Bravecto, Bravecto Plus, Coxevacand Osurnia, and recommended changes to their product information.

The Committee also reviewed the PSURs for Cytopoint and Vectormune ND and concluded that no further action or changes to their product information were required.

The Committee finalised the preparation of the Presidency CVMP and joint CVMP/CMDv meetings to be held under the Finnish Presidency of the EU, on 25-27 September 2019. The meeting will be conducted under the theme 'Responding to challenges for the veterinary medicines network 2019-2020: New veterinary legislation' and the discussions will focus on:

- Promoting product availability with emphasis on the provisions concerning limited markets
- Implementation of the Regulation 2019/6 with emphasis on the new role for the Pharmacovigilance Working Party and the responsibilities of CVMP and CMDv including communication on issues of common interest.

The EMA is launching a new webpage outlining the Agency's progress in implementing the new Veterinary Medicines Regulation.

On this <u>Web page</u>, stakeholders can find all relevant information concerning EMA's scientific and technical recommendations to the European Commission that will feed into <u>delegated acts and implementing acts</u> as part of the implementation of the <u>legislation</u>, as well as updates on other activities such as preparing for progress in implementation.

# OTHER ISSUES

### Latest news on animal disease at EU level

### Europe on high alert as African Swine Fever (ASF) sweeps through Asia

Anca Paduraru, EU spokesperson for public health and food safety, stated that EU member states should apply strict biosecurity measures to combat African Swine Fever (ASF). "All affected member states must apply the <u>European legislation</u>. This includes prevention and control measures to be applied where ASF is suspected or

confirmed, either in holdings or in wild boars," she said. According to the EU Food and Safety Authority (EFSA), nine EU member states (Belgium, Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland and Romania) were touched by the disease at the beginning of august. The union of EU farmers and cooperatives, Copa-Cogeca, said that outbreaks were also notified in Serbia, and Slovakia. Furthermore, this organisation declared that the situation in Asia was catastrophic, with outbreaks reported in China, Vietnam, Cambodia, Mongolia, North Korea and Laos.

### A vaccine to eradicate ASF?

In a letter sent to various environment and ecosystem managers of Belgium, Professor D. Desmecht, a member of the strategic committee "ASF" of the Walloon region, called the ASF virus a worldwide problem. He underlined the four requirements that an ASF vaccine must have in order to be effective. The desired vaccine should (i) stop the contagion, (ii) spread little in the wild, (iii) be compatible with animal welfare and (iv) be genetically stable. He added that the ideal vaccine should be effective after administration by ingestion. Finally, he advanced that the scientific challenge is considerably more difficult than for other animal diseases because the virus targets the immune system and because it is genetically more plastic than expected for a DNA organism.

#### Research gap analysis on African swine fever

A <u>survey</u> from EFSA sought to take into account the opinion of a maximum of stakeholders in the context of African swine fever. The four main points in which participants identified a general lack of knowledge that emerged from this survey were wild boars, ASF virus, biosecurity and surveillance. Veterinary services emphasized the importance of identifying the sources of introduction of the virus into a new country. Improved communication and disinfestation methods as well as the establishment of an ASF management structure and further research into the transmission of the virus have also been addressed.

#### 16th Animal Health and Welfare Network

The 16<sup>th</sup> Animal Health and Welfare Network that took place on the 1<sup>st</sup> of august in Parma manly focused on the SIGMA project.

The SIGMA project originates from an internal review, performed by the Animal Health and Welfare (AHAW) team (EFSA Animal and Plant Health unit), on the current data standards and data collection practices related to certain animal diseases (namely, Avian Influenza, Africa Swine Fever, Lumpy Skin Disease, Echinococcus multilocularis). This was triggered by requests from data providers to simplify the process which, at present, entails a considerable effort for the countries submitting data to EFSA for risk assessment purposes. In addition, EFSA identified the benefits to be gained from a higher degree of standardisation of the data which should be the most up to date and submitted within a timeframe that can be extremely short in case of an outbreak.

The pilot phase of the SIGMA project started officially in 2018 and was presented in May 2018 to the members of the AHAW Network. After one year of activities, EFSA wanted to provide an update by illustrating the achievements (the data model, the country cards) and the ongoing activities (the technical questionnaires on the data flows, the study on the legal implications). In addition, EFSA aimed at gathering feedback from the countries engaged in the pilot (Spain, Italy, Croatia, Romania, Austria, Estonia and Bulgaria) and at understanding all possible concerns and suggestions from the countries that did not engage. The report published by EFSA contains all the elements listed above and can be considered an up-to-date overview of the SIGMA project.

# Retrospective analysis of vector-borne infections in dogs after travelling to endemic areas (2007-2018)

The Federation of European Companions Animal Veterinary Association (FECAVA) published, on august 28, an <u>analysis</u> of vector-borne infections in dogs after travelling to endemic areas for the period 2007-2018. The objective of this retrospective study was to evaluate whether dogs were exposed to a corresponding risk of

infection when travelling to regions in the Mediterranean area and south-eastern Europe, which are endemic for these pathogens.

The researchers have discovered that 13 % of dogs in the retrospective study that had travelled to endemic countries were tested positive for at least one vector-borne pathogen. Furthermore, they have exposed that risks of infection also exist when the stay occurs for a limited time.

# Skin and ear health in a group of English bulldogs in Finland – a descriptive study with special reference to owner perceptions

The Federation of European Companions Animal Veterinary Association (FECAVA) published, on august 28, a <u>cross-sectional study</u> that describes the dermatological health status of a group of 27 English Bulldogs (EBs) and that compares the results with owner perceptions and its possible impact on quality of life (QoL). Computed tomographic (CT) findings of the ear canals were compared between EBs and mesaticephalic dogs. The results showed that all 27 EBs had abnormal findings on dermatological examination, but that 37% of the owners had not recognized skin or ear signs.

#### Case of rabies diagnosed in a puppy in Ceuta, Spain.

Ceuta, the Spanish autonomous city on the north coast of Africa, has confirmed a case of rabies this June in a three-month-old puppy which was illegally brought to a shelter from Morocco. The facilities, where the puppy was kept were closed, over 100 animals were quarantined and some killed. 36 people in relation to the facilities have been evaluated and vaccinated if necessary. The authorities are calming the population, since the dog was under control in an enclosed area all the time. Although the city has extended the operational vaccination campaign, it is free and mandatory for all cats, dogs and ferrets.

This is the first case of rabies in Ceuta after 2012, when it was confirmed in a stray dog. The authorities are now investigating the border control failure and plan to reinforce it.

# Latest updates on animal welfare at EU level

# A call from the civil society to denounce the conditions of transport of some animals

The World Farm Protection Association Welfarm relayed on August 21 a <u>video</u> denouncing the conditions of transport of calves between Lithuania and Israel. A report specifies the carrier's failure to comply with the animal protection regulations during transport.

According to Eurogroup for Animals, the video was sent to the European Commissioner. The organization calls on the Commission to put an end to the transport of animals to third countries.

# 360<sup>th</sup> session of the Intergroup on the Welfare & Conservation of Animals

On September, 19<sup>th</sup> the 360<sup>th</sup> session of the Intergroup on the Welfare & Conservation of Animals took place. This meeting was mainly focused on the appointment of the new President (Member of the European Parliament Anja Hazekamp) and Honorary President (Member of the European Parliament Sirpa Pietikäinen), the appointment and reappointment of the Vice Presidents as well as setting up priorities for the new legislative

term. These new priorities will gravitate around the different legislations concerning farm animals such as the <u>General Farming directive</u>, the <u>Broiler Directive</u> and the new Common Agricultural Policy.

# Brexit: Vets concerned over animal medicines in no-deal

An <u>official document</u> concerning a no deal Brexit assessment underlines the possibility of disruption in importation of medicines for veterinary use that would have potential detrimental impacts for animal welfare as well as for diseases which are spread between animals and humans.

The government stated that animal medicines are classed as "category 1" goods, which would be prioritised if there was disruption at the border after a no-deal Brexit.

According to the British Veterinary Association (BVA), there are some concerns about the availability of some animal medicines in the case of a no-deal Brexit especially short-shelf life products, such as vaccines. As a matter of fact, products which are short shelf-life products need the supply chain to be maintained on a pretty constant basis. Important problems could arise from such a situation especially in autumn, when farms start to bring cattle into sheds to avoid the worst of the winter weather, thus increasing stocking density and cow to cow contact, therefore creating a higher risk of infectious disease transmission such as pneumonia.

Zoo animals and pets would also be affected by a no-deal Brexit if there isn't a supply of vaccines for an animal to get its booster at a particular time. The BVA advices pet owners to talk to their vets if they are concerned.

The UK National Office of Animal Health is concerned about a potential increase in the risk of spreading of a disease if preventative medicines are not available.

Finally, the Royal College of Veterinary Surgeons fears a decline in veterinary workforce, as half of new vets are recruited outside of the UK, from an EU Member State each year.

## A new 'Horse group' for the Members of the European Parliament.

The European Horse Network (EHN) has confirmed the Belgian EU Member of Parliament, Mrs. Hilde Vautmans, as the new chairman of the Member of the European Parliament (MEP) horse group.

The MEP-Horse Group was founded in 2011 by the British delegate Julie Girling, as part of the European Horse Network (EHN), with the aim of giving the horse sector more visibility on the European political agenda. Since then, the group has worked on numerous European regulatory issues and texts such as the common agricultural policy, veterinary medicines, consumer sales, the VAT reform and the Brexit.

Mrs Vautmans, who succeeds the French MEP Jean Arthuis, wants to encourage some of her new parliamentary colleagues to attend the first meeting of this working group of the EU Parliament in Brussels on 15 October. Its main focus is to emphasize the many strengths of the European horse sector and to propose political actions to support and further develop them.

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