EU NEWS

November 2023

UEVP

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

November was marked by two key events:

Firstly, from an animal health perspective, antimicrobial resistance issues are still key to European debates. Several European agencies and authorities (EEA, ECDC, EFSA, ECHA and EMA) jointly reaffirmed their commitment to supporting the "One Health" approach, in order to better prevent risks at source in order to guarantee health safety. In line with this, in a statement issued in mid-November, the European Commission reiterated its commitment to the fight against antimicrobial resistance, and called for "urgent and ambitious" measures to be taken, as supported by the veterinary profession

Furthermore, from an animal welfare standpoint, the European Commission is expected to publish its legislation proposal on the welfare of animals during transport before the end of the year. While we welcome this first decisive milestone, we are committed to following the further work to which the European Commission has engaged itself, and which will focus in particular on the animal welfare of breeding animals, during slaughter, and on the issue of animal welfare labelling.

As the year comes to an end, I would like to wish you all a very happy holiday season!

Volker MOSER, 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 7th to 9th November 2023.

The Committee adopted positive opinions for variations requiring assessment concerning quality-related changes for **Equioxx Onsior**; **Simparica Trio, Felisecto Plus, MiPet Easecto, Simparica, Stronghold Plus** and **Vectormune ND, Newflend ND H9.**

Also, the Committee adopted positive opinions for variations requiring assessment to align the product information with the latest version (9.0) of the QRD template for **Credelio Plus**; **Eravac**; **Eryseng**; **Eryseng Parvo**; **Evalon**; **Evant**; **Hiprabovis IBR Marker Live**; **Meloxoral**; **Mhyosphere PCV ID**; **Nasym**; **Nobivac Myxo-RHD Plus**; **Nobivac LeuFel** and **Leucogen; Rhiniseng**; **Startvac**; **Suvaxyn Circo+MH RTU**; **Suvaxyn Circo**; **Ubac** and **Vepured.**

The Committee included **Varroa destructor calmodulin gene-specific double-stranded interfering RNA EP15 (naked unmodified dsRNA)** as a new entry in the list of chemical-unlike biological substances not requiring a full Maximum Residue Limit (MRL) evaluation in accordance with an EU Regulation and adopted a revised list of chemical-unlike biological substances not requiring an MRL evaluation.

The Committee classified a product for cats on alimentary tract and metabolism as intended for a limited market and eligible for authorisation under the Regulation on veterinary medicinal products, and a product for horses on musculo-skeletal system as intended for a limited market but not eligible for authorisation under the same Regulation.

After a public consultation, The Committee adopted a revised reflection paper on the environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs.
The Committee adopted a concept paper on the revision of the guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches for release for a 3-month period of public consultation.
Finally, the Committee has adopted a new procedure concerning the number of invented name requests. From 1st January 2024 they will be limited to two in order to make the procedure for checking invented names more efficient. This decision has no impact on already submitted invented name requests, or already accepted invented names.

Latest news on antimicrobial resistance at EU level

Organisation of a conference on the "One Health" approach by the European Commission

On 13th November 2023, the European Commission's Directorate-General for Health and Food Safety organised a conference entitled
"*One Health for All, All for One Health"* to review the situation and discuss the future of the approach.

The day was divided into several sessions, one of which was specifically dedicated to antimicrobial resistance. This session brought together several speakers, including:

- Sandra GALLINA: Director General in the Health and Food Safety Directorate of the European Commission
- Christopher FEARNE: Deputy Prime Minister and Minister for Health of Malta
- Marjolijn SONNEMA: Director General of the Dutch Ministry of Health, Welfare and Sport
- Dr. María JESÚS LAMAS DÍAZ: Director of the Spanish Agency for Medicinal Products and Medical Devices and member of the Management Group of Heads of Medicines Agencies
- Dame Sally DAVIES: UK Special Envoy for Antimicrobial Resistance, member of the UN Global Leaders Group on Antimicrobial Resistance and former Chief Medical Officer for England.
- Osama EL-LISSY: Secretary of the International Plant Protection Convention.
- Dr. Robert Leo SKOV: Specialist in infectious diseases at the Statens Serum Institut, President and Secretary General of ESCMID, Scientific Director of ICARS.
- Francesco IMPERI: Professor of Microbiology at the University of Rome (Italy).

The speakers shared their expertise on the issue of antimicrobial resistance, as well as their recommendations on how to achieve better results. Overall, they stressed the importance of communication and collaboration between stakeholders. However, they considered that this was not enough, and called for more sustained action to move the current situation forward. Regarding technology, its role should be placed more at the service of health. In this context, artificial intelligence was cited as a means of facilitating scientific studies. Emphasis was also placed on the importance of increased monitoring by several stakeholders, with a view to collecting data that will enable research to progress. Sandra GALLINA (Director General of the European Commission's Directorate General for Health), noted that a lack of financial resources could hamper progress in research, but remained optimistic about the future in this area.

Following this event, the European Environment Agency (EEA) published a statement of belief setting out a joint commitment by the EEA, the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA) and the European Medicines Agency (EMA) to support the "*One Health*" approach. They believe that it is essential to tackle the factors that degrade the environment and to prevent risks at source in order to guarantee health safety.

the European Commission reiterated its commitment to the fight against antimicrobial resistance in a statement on 17th November 2023. In the run-up to "*European Antibiotic Awareness Day*", new data published by the ECDC showed that "*progress has been made between 2019 and 2022 towards the overall goal of reducing antimicrobial use by 20% by 2030*".

However, Stella KYRIAKIDES, European Commissioner for Health, reaffirmed the need for “urgent and ambitious” measures, pointing out that antimicrobial resistance was a key element of the proposal for a review of pharmaceutical legislation presented last spring, which includes the objective of reducing the consumption of antimicrobials in humans by 20% and halving global sales in the EU of antimicrobials used in farm animals and aquaculture by 2030.
Various stakeholders have taken position on the subject, such as the federation of Veterinarians of Europe (FVE) or AnimalHealth Europe also calling for better supervision and a reduction in antimicrobials.

Latest news on animal health at EU level

Publication of two implementing decision about new outbreaks of avian Influenza in European regions

On 13th November and 24th November, the European Commission published two new implementing decisions concerning new regions affected by avian influenza.

The regions placed under protection and surveillance are as follows:

- **Bulgaria**, in the regions of Veliko Tarnovo, Pazardzhik, Dobrich and Haskovo
- **Romania**, in the country of Teleorman
- **Denmark**, in the Slagelse municipality
- **Hungary**, in the country regions of Hajdú-Bihar, Szabolcs-Szatmár-Bereg, Bács-Kiskun, Békés, Borsod-Abaúj-Zemplén, Csongrád-Csanád and JászNagykun-Szolnok.
- **Netherlands**, in the Noord-Holland and Utrecht provinces
- **Italy**, in the Veneto region
- **Croatia**, in the Brod-Posavina county
- Finally, **Germany**, in Lower Saxony, Mecklenburg-Vorpommern and Thuringia states.

Adoption by the European commission of an implementing regulation laying down special measures to tackle African swine fever and publication of a report by the European Union's publication office

On 31st October, the Commission published an implementing regulation on the development of African swine fever in Croatia. The situation in the Karlovacka region has not improved and must be placed in zones I and II.

Moreover, in November, the European Union's publication office published a report on the progress and challenges of the development of an African swine fever vaccine.

The main challenges developed in the report to vaccine development are as follows:

- **The African wsine fever virus (ASFV) is a highly complex pathogen.** The physical size of the virus is huge, implying that it has a lot of proteins that supply a high ability to avoid and escape the immune system.
- **The identification of ASFVproteins** that induce a fully protective immune responses in pigs, known as protective antigens, **has not yet been reached.**

- **The extent of ASFV strain variation isproblematic,** as the virus causes persistent, long-term latent infections in warthogs and in pigs surviving acute viral infections.
- The European Food Safety Authority (EFSA) conducted a gap analysis on African swine fever in July 2019 and identified several challenges:
  - The lack of basic proteomics research in this field.
  - The high propensity for ASF transmission and spread due to the interaction of wild boar with domestic livestock.
  - The fact that ASFV is capable of surviving in different matrices, which complicates its eradication and containment.
  - The need for increasing awareness and compliance with existing control measures, in order to achieve suitable biosecurity levels.
- The difficulty in **finding locations within Europe that would receive authorisation for performing field trials involving ASF.**
- **The lack of internationally harmonised guidelines** for assessing the quality, safety and efficacy of ASF vaccine candidates.

The document sets out the various patents filed for the vaccine and concludes by proposing a roadmap for accelerating the vaccine's development, including the following elements:

- Establish **minimum acceptance criteria;**
- **Select candidate vaccines** to be tested in a double blind set up**;**
- Establish a **plan for scaling-up vaccine production**.

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

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On 31st October 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.

In this context, Greece has informed the European Commission of the current situation regarding sheep pox and goat pox on its territory, following an outbreak of this disease in sheep and goats **on the island of Lesvos**, confirmed on 24th October 2023 - in accordance with Delegated Regulation 2020/687.

The **island of Lesvos** in Greece has therefore been placed under a **surveillance and protection zone**. This decision will have to be reviewed at the next meeting of the Standing Committee on Plants, Animals, Food and Feed.

Publication in the Official Journal of the European union of a delegated regulation on the animal health requirements for movements within the Union of terrestrial animals

On 14th November, a **delegated regulation as regards certain animal health requirements for movements within the Union of terrestrial animals** was published in the Official Journal of the European Union and officially came into force on 24th November 2023. The aim of this text is to combat the spread of epizootic haemorrhagic disease.

More specifically, the text authorises the movement of animals to other EU states, even if they come from a place where the virus has been reported, provided that the animals come from delimited areas. The text thus establishes "***seasonally free zones***" (SFZ), meaning zones where a period free from contamination has been demonstrated by the state, as well as "***vector protected establishments***", in other words establishments where measures have been put in place to prevent the spread of epizootic haemorrhagic disease (EHD).

OTHER ISSUES

Latest news on international trade

Update on EU trade negotiations with Australia, South Africa, New Zealand and Mercosur

In recent weeks, negotiations on trade agreements between the European Union and Australia, South Africa, New Zealand, and Mercosur have evolved as follows:

a. New Zealand

On 22nd and 27th November, the European Parliament and the Council respectively approved the trade agreement between New Zealand and the European Union by large majority. New Zealand's ratification is scheduled for early 2024.

According to the European Commission, this trade agreement is "*the most ambitious*" ever concluded in terms of commitment to sustainable development. Indeed, the Free trade agreement (FTA) liberalizes trade in most animal products and should therefore further stimulate animal agriculture in the EU and New Zealand. The FTA only **covers grass-fed animals, which explicitly excluding feedlots**. This condition is motivated by animal welfare and sustainability concerns. The FTA is also the first to include sanctions in its Trade and Sustainable Development (TSD) chapter and the first to include a chapter on animal welfare cooperation. However, these provisions are not binding.

b. Australia

Several European associations (including Eurogroup for animals, Australian Alliance for Animals and Animals Australia) have called on the European Union and Australia to **include animal welfare in their trade agreement.**

As the negotiations for this free trade agreement draw to a close, the welfare associations are stressing the importance and necessity of including this objective in their trade agreement, as the only way to ensure that these provisions will be respected. In their view, existing trade agreements exacerbate rather than reduce the negative consequences of intensive farming.

Indeed, Australian beef destined for the European Union could come from Australian "*feedlots*", whose practices could cause respiratory and digestive problems in the animals. They therefore reiterate that it is essential that the European Union and Australia establish preferential prices for beef from more sustainable feeding systems, and ban beef from such feedlots.

Among the most sensitive outstanding issues is that of animal welfare during transport: European associations consider Australian regulations on the transport of animals over long distances to be "*minimal and almost unenforceable*" and are therefore calling for European standards in this field to be taken into account in the trade agreement.

At the last meeting on 29th October, which was initially intended to be the "last meeting" before agreement, these issues compromised the outcome of the discussions. While the opening of the European market to Australian meat imports seemed to have stabilized, the outcome of the negotiations now seems more uncertain.

c. Mercosur

Regarding the negotiations between the European Union and MERCOSUR are intensifying with a view to signing the agreement before the new Argentine president Javier MILEI takes office on 10th December.

Nevertheless, **Eurogroup for animal** is calling for improvements on the animal welfare and environmental protection aspects of the treaty. In their view, the treaty in its current stance could reinforce the intensification of animal farming, in particular beef and poultry production, and increase the risks of deforestation and human rights violations due to the EU's demand for commodities such as soya, beef and poultry.

The Eurogroup for animal's proposals are as follows:

- Condition preferential access for all animal products.
- Include an ambitious chapter on Sustainable food systems, recognising animal sentience, and the importance of animal welfare for citizens and to achieve sustainable food production.
- Create meaningful cooperation mechanisms on animal welfare, setting clear objectives and roadmaps.
- Include a state-of-the-art trade and sustainable development chapter, with the possibility of sanctions.

Eurogroup for Animals' position is based in part on information gathered by the European Commission. Indeed, the European Commission has carried out an audit (here and there) of facilities producing horsemeat for the European Union market in Argentina and Uruguay, in order to monitor the implementation and enforcement of EU legislation on food safety, animal health and welfare purposes. The results gathered were considered "rather worrying".

According to the report, in Uruguay, there is currently no traceability to determine whether horses have received veterinary medical treatment that could compromise their health and should prevent them from entering the food

chain. In addition, despite the ban on Brazilian horsemeat imports into the country, unidentified horses from Brazil have been found to enter the Uruguayan food chain.
In Argentina, shortcomings have also been noted in terms of horse identification and traceability, as well as the reliability of supporting documents. To date, guarantees of compliance with EU medical treatment requirements are based solely on sworn declarations by owners, with no further verification by the competent authorities.

In this context, imports of horsemeat from Argentina and Uruguay should be suspended.

d. South Africa

On 22nd November, the European Commission adopted an implementing decision to repeal a previous decision authorizing the import and admission of horses from Latin America. The previous authorization had been given on the grounds that the Cape region was not affected by African horse sickness.

Latest news on animal welfare at EU level

Leak of the Commission's proposal for legislation on the welfare of animals during transport and preliminary information on its content

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On 30th November, **the first details of the legislative proposal on animal welfare during transport** - expected on 6th December - have been published by the European specialised press. The main aim of the measures is to limit journey times and transport conditions.

More specifically, the text addresses the following issues:

The European Commission does not appear to propose a ban on live animal exports to third countries. This measure, strongly supported by Intergroup MEPs and animal welfare organizations, had been deemed to have "*very negative consequences for the EU economy*" following the publication of the impact assessment in April 2023. The measure was also criticized in the Council by eight member states, including France.

On this point, the European Commission is proposing that "*organizers of animal transport*" to third countries should be subject to the same obligations as for intra-European journeys.

Other key measures include :

- **Limitation of journey times according to species and destination** :
    - For cattle, pigs, goats, and horses: The proposal mentions a journey time limit of 21 hours, with a mandatory 1-hour break after 10 hours of travel. If, at the end of the journey, the animals have been unloaded for at least 24 hours, the journey can be extended by a second period of 21 hours, under the same conditions. However, if the convoy's destination is a slaughterhouse, the maximum journey time must be 9 hours. Exemptions may be considered if there is no suitable slaughterhouse within the initial radius.

- For poultry: The proposal mentions a journey time limit of 12 hours, or even 10 hours for hens at the end of their laying period. For chicks, the limits will be 24 hours, provided the journey takes place within 48 hours of hatching.
- More specifically, for unweaned animals: The maximum journey time will be 8 hours, with the possibility of a derogation of up to two successive periods of 9 hours, only if the means of transport has a system for feeding the animals.

- **Specific provisions for difficult weather conditions**:
  - If transport takes place in weather conditions close to 0°C, the vehicle must be equipped with controlled ventilation and be covered, to avoid exposing the animals to the risk of chilling. If temperatures fall below -5°C, transport time must be limited to 9 hours.
  - In contrast, if temperatures are high, the European Commission encourages the introduction of "*controlled time windows*". Between 25°C and 30°C, transport time between 10:00 and 21:00 may not exceed a total of 9 hours. Above 30°C, only journeys after 21:00 (and up to 10:00) will be authorized.

- **The improvement of transport conditions:** additional obligations and criteria are set out to define whether an animal may be considered fit for transport, or regarding vehicle quality (to avoid possible animal injuries). For example, one of the measures set out in the annex aims to define the minimum available space to be respected (a measurement is calculated according to the type and weight of the species). In addition, the loading and unloading of animals must be supervised by a veterinarian to ensure compliance with the rules set out in the Regulation.

- **Fitness for transport:** Ill or injured animals considered fit for transport must meet certain veterinary conditions:
  - For "*slightly ill or injured*" animals where transport would not cause further damage, a veterinary notice must be provided for verification.
  - For animals undergoing veterinary treatment, transport must be carried out under veterinary supervision and only if it does not cause the animal any additional suffering.
  - For animals that have undergone veterinary surgery: transport is possible if the wounds are not bleeding, and measures are in place to limit contact with the wound.
  - If an animal falls ill or is 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 given under veterinary supervision.
  - Cats and dogs must receive the necessary preventive veterinary treatment before transport.
  - In the case of aquatic animals showing signs of abnormal clinical signs, they must be killed with prior stunning, or isolated and examined by a veterinarian.

Finally, Member States are invited to determine the penalties applicable to breaches of the Regulation, and to take all necessary measures to ensure their implementation. The penalties provided for must be "*effective, proportionate and dissuasive*". However, Member States are required to notify the European Commission without delay of these arrangements and measures, as well as any subsequent changes affecting them.

Based on the data recorded in TRACES, the European Commission will have to publish, 5 years after the date of entry into force of the regulation (and every 5 years thereafter), a follow-up report on the animal welfare situation in the Union as regards transport.

Following this, Eurogroup for animals published an article on 1st December about the leaked draft legislative proposal. In response, the organisation deplored the general aspect of the legislative proposal, which puts trade and profit before animal welfare. In particular, it regretted that exports of animals to third countries are authorised, and under questionable conditions: "*According to the new draft rules, the operators who should be reporting any animal welfare problems are the same people in charge of the animals during the journey. The same people who are profiting from the business. We can only imagine how eager these operators will be to report their own violations to the competent authorities*."

Furthermore, Eurogroup for animals considers that the proposal lacked scientific coherence and consistency, particularly with regard to journey times for unweaned animals, temperatures, and a general lack of precision with regard to "scientific" aspects. It also added that the proposal does not provide for concrete, species-specific means of assessing fitness for transport.

Adoption by the Council of a regulation on the labelling of organic pet food

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On 18th October 2023, the regulation on the labelling of organic pet food **was published in the Official Journal of the European Union and came into force.**

As a reminder, on 9th October 2023, the Council adopted this regulation as part of the Farm to Fork strategy presented by the European Commission in May 2020, aimed at "*making food in Europe healthier and more sustainable*". More specifically, this strategy was designed to promote organic production, with the aim of achieving a 25% share of European agricultural land by 2030.

Thus**, the aim of this regulation is to bring the rules for labelling pet food into line with those for labelling human food.** The novelty consists in the addition of a logo on the labelling of pet food, provided that 95% of the agricultural ingredients are organic. The aim of this logo is to make it easier for consumers to identify the composition of foodstuffs. The regulation also provides for a six-month transition period to allow producers of these domestic products to include the organic logo on their products.

Agreement between the European Parliament and the Council on the revision of the Regulation on EU geographical indications for wines, spirit drinks and agricultural products

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On 24th October 2023, the European Parliament and the Council reached an agreement to revise and strengthen the system of geographical indications (GIs) for wines, spirit drinks and agricultural products.

As a reminder, GIs are used to protect the names of products from specific regions, or with specific characteristics, qualities or reputations, against copying or fraud. In particular, they aim to certify that these products have been produced to high standards in their region of origin.

The aim of the new regulation is to strengthen the current GI system, **in particular by recognising sustainable environmental, economic and social practices, including animal welfare, for example through practices designed to preserve local animal species.**

Announcement by the European Investment Bank of a €40 million investment in technology to avoid the slaughter of male chicks

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On 3rd November, the European Investment Bank (EIB) announced that it had signed a €40 million loan agreement with Dutch AgriTech company In Ovo for the period 2023-2026, to develop its 'Ella' technology, which can prevent the slaughter of day-old chicks. Its aim is "*to identify the sex of eggs at an early stage, thus enabling hatcheries to hatch only laying hens and eliminate the need to cull male chicks directly after hatching*", explains the European Commission in a press release.

Stella Kyriakides, European Commissioner for Health and Food Safety, declared that, thanks to this technology, "*we will avoid the systematic killing of millions of male chicks throughout the European Union. This is an important step in our work to raise animal welfare standards in the EU"*.

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