ANIMAL HEALTH ADVISORY COMMITTEE

Working Group of the Advisory Group on the Food Chain, Animal Health and Plant Health

MONDAY 24 NOVEMBER 2014, 10.00 H – 18.00 H

Berlaymont Building – Rue de la Loi 200 – 1049 Bruxelles, Room Jean Rey

SUMMARY

Note: the summary below covers discussions after and beyond the presentations which are already available embedded into the online agenda:
https://ec.europa.eu/food/sites/food/files/animals/docs/comm_ahac_20141124_agenda.pdf

Morning session 10:00-13:00

Introduction, opening: A. Laddomada Head of Unit G2 Animal Health - DG SANCO

1. **Commission Proposal for a Regulation on veterinary medicinal products,** SANCO D6

After the presentation, EAZA welcomed the proposed legislation and said that zoos work with minor species and in fact the use of medicines in accordance with the marketing authorisation is minimal adopting at present the "cascade". The Commission informed that the legislation provides more flexibility for off-label use of medicines and provides best choice of veterinary medicines available on the market. It is predicted that revision of the legislation will encourage the availability of more products on the market and therefore reducing the need for use of off-label products.

EUROGROUP supports the proposal and states that the document contributes to the animal welfare as more species may be treated due to the access to a wider range of medicines.

EGGVP welcomed the proposal and asked for clarification on the way forward for the adoption and implementation of the legislation. The Commission informed that the proposed Regulation will be a basic act and provides the basis for delegated/implementing acts. It has been developed to be applicable for a 15-20 year period without requiring legislative amendments. The delegated and implementing acts incorporate technical and procedural details that may require earlier revisions. The choice to include issues for either in the basic act or in the secondary legislation is mainly up to the co-legislators. Detailed acts would be likely at a later stage (2 years approximately). In any case, consultation with stakeholders is important to DG SANCO, and is a well-established practice, moreover also foreseen in new rules.

FVE applauded the Commission for the forward looking Proposal and expressed concern that the internet sales of veterinary medicines may not enough to regulate the market and might jeopardize the fight against antimicrobial resistance (language issues, genuineness of the prescribing vet and also to ensure that the animals are actually under their care). FVE suggested that the Commission may consider diagnostics in future veterinary legislation which is not regulated in Europe and currently adopted in the human field. The Commission

informed that the legal framework available for internet sales for "human" medicines was adopted for veterinary medicine. There is no possibility to prevent illegal sale by internet but the proposal provides an alternative legal way to citizens and farmers to buy effective and safe medicines by internet, by "ring-fencing" authorised internet retailers. As for veterinary prescriptions, there are currently no EU rules on the content of veterinary prescriptions. Therefore some harmonisation is necessary by establishing on EU level minimum requirements. The proposal does not specify the use of language in the issuance of veterinary prescriptions. Rules for diagnostics have been discussed in detail by the Commission and it was decided that it is not appropriate to develop EU legislation due to subsidiary and proportionality reasons.

IFAH-EUROPE: applauded proposal but considered that the value of the foreseen data protection measures in supporting and stimulating innovation is low. IFAH also questioned the added value of the new "cascade", as human/veterinarian medicines can already be used off-label. The Commission informed that the proposal provides the choice to veterinarians to use off-label the best authorised products available on the market, taking into account public and animal health. It was underlined however that off-label use will have to comply with the specific provisions included in the proposal for this type of use of medicines. IFAH highlighted that new rules banning animals from clinical trials from entering the food chain are too strict: it is a waste of resources and e.g. especially dairy farmers may be reluctant to cooperate. The Commission informed that the requirements for clinical trials is mainly the competence of Member States, only main elements are proposed, for example the provisions for animals used in clinical trials entering the food chain. IFAH supports proposed SPC (Summary of Product Characteristics) harmonisation but raised concern of the increase in costs of this harmonisation exercise particularly on environmental side which may be counterproductive. The Commission is aware of these costs and the next step is discussion with the European Parliament and Council.

OIE congratulated the Commission on the proposal and supports anti-fraud arrangements reducing dangerous medicines on the market worldwide. The proposal should address administrative burdens but not to make fraudulent activities easier. The Commission reiterated that the legal framework will provide a more efficient and effective control mechanism with obligatory cooperation of Member States with inspections.

FESASS views Commission's proposal in a favourable light as regards to medicines available for minor species and providing for a more efficient framework to the "cascade" system. Fraud and the internet are 2 major problems. So we need guarantees across the medicines supply system and a strong legal basis at European level. The Commission clarified that the proposal clearly states that the use of medicines must in accordance with market authorisation with specifying the derogations. The proposal addresses internet fraud by providing basis to list companies authorised to sell veterinary medicines on the internet in Europe. It will be illegal for customers to buy products from non-authorised retailers. The proposal will facilitate for authorities to take action to illegal activities.

2. State of play of EU AMR Action Plan, SANCO G4

After the presentation OIE informed that an *ad hoc* Committee is carrying out research on AMR and stressed the importance for work continuity on this dossier. OIE stated that most of the resistant microbes originate from outside the EU and the Commission should explore these avenues. OIE and the Commission are working closely with third countries, particularly east of the Mediterranean were there are alarming rates of antibiotic resistant pathogens. The

EU delegation in Paris deals with OECD subjects, the Commission has its support. Commission welcomed support and agreed on the importance of the international scenario.

EUROGROUP welcomes comprehensive presentation and stressed the need of measures to address antibiotics reduction in intensive farming. The Commission stressed the importance of guidelines to be published next year. The Guidelines will include a theoretical section translated in all EU languages and an annex incorporating practical examples of prudent use of antimicrobials by Member States and stakeholders. The Commission invited stakeholders to forward data for inclusion in the annex.

EGGVP queried if data collection in ESVAC project by species carried out at farm will substitute collection at marketing holders and distributors. EGGVP suggested transfer of some funding/joint action for training programmes under "Better Training for Safer Food" to stakeholders. The Commission informed that EFSA has an on-going pilot project on AMR. The sole collection of data at farm is not recommended as it is a time-consuming process: a combination of both is perceived on the longer run. BTSF for stakeholder training is not provided but smaller actions (e.g. with FVE) are ongoing.

BEUC welcomed the update and with reference to Action 2 & 3 (appropriate use of antimicrobials in veterinary medicine) requested clarification on "inappropriate use". BEUC proposed that "critical antimicrobials" should be more defined. The Commission informed that "inappropriate use" is included in the definition "prudent use". Regarding "critical antimicrobials", reference was made to the established lists by WHO and OIE incorporating animal and public health and EMA was consulted on their prioritisation – critical and non-critical. Furthermore, Article 32 of the veterinary medicinal proposal refers to "certain antimicrobials" not "critical" and the definition will be developed in the implementing act.

FVE reiterated the necessity to provide BTSF trainings to stakeholders and inquired about the update of the future guidance document. Commission confirmed that the annex of the guidance document is planned to be regularly updated.

3. Commission proposal on medicated feed, SANCO G1

Participants welcomed the presentation and the Commission's efforts. However, clarification for the expression "preventive" was sought or even the replacement by "prophylactic". FEFAC congratulated the Commission on the harmonisation of legislation which is advantageous to farmers but also challenged the general duty for the manufacturer of medicated feed to guarantee compatibility as well as to reduce carry- over. The manufacturers are not in the position to undertake specific tests for each feed material or feed additive to be mixed with the veterinary medicine. Instead, the authorisation of the veterinary medicines for MF production should contain the respective information concerning compatibility with feed and incentives to reduce carry over (better formulation etc.). The Commission acknowledged FEFAC's concerns. In its reply explained that compatibility and homogeneity are requirements for Medicated Feed but SPCs of the veterinary medicinal products are expected to contain data on these. Stability provisions in VMP authorisations are also contribute to compatibility. On the issue of preventive use of medicated feed in antimicrobials, the wording "prophylaxis" may be used instead. The definition is being discussed with AMR colleagues to apply same terminology. There are also debates on the wording "prevention and treatment" OR "prevention or treatment".

4. Brucellosis subgroup of the Task Force on the eradication of animal diseases, SANCO G5 + Chair of the subgroup

After the presentation the Commission highlighted the importance of these long-term eradication efforts which steadily deliver good results. FESASS stressed that brucellosis in

wild fauna is an issue and asked whether and if so, how these are investigated or are considered for better biosecurity management. The Chairman of the brucellosis subgroup explained that they have evaluated the situation in different Member States and in many countries prevalence is more related to domestic livestock. In any case the task force gives recommendations to improve the interface between domestic and wild animals. For example outbreaks in France occurred in domestic livestock and experts are analysing their implications in wild fauna.

Afternoon session 14:30-18:00

5. EFSA scientific opinions, EFSA

- **on Porcine Epidemic Diarrhoea (PED)**

Following the presentation by EFSA, many thanked the EFSA for its welcome and valuable work. EAPA indicated that some of the testing they did (ELISA on spray dried plasma from France, the Netherlands and Germany) were all negative; which suggested the absence of population immunity. The Commission clarified that this EFSA report was already discussed with the MS in October.

- **on sheep and goat pox**

After the presentation by EFSA EUROGROUP pointed out the animal welfare aspect and that the use of inactivated vaccine in outbreak situations should be considered to avoid unnecessary culling. Also wondered if exports to 3rd countries would have a boomerang effect causing the virus to come back. The Commission informed that a vaccine has to be safe and efficient and there is lack of such today, furthermore a cost-benefit analysis should indicate whether it is better to use it or not. As regards exports, the Commission stressed that the disease is endemic in neighbouring countries, i.e. not the EU is exporting it there, rather restrictions on imports are necessary to prevent it from entering. Strict measures have been implemented to control the disease in the EU: the outbreak in Bulgaria has been eradicated and in Greece stringent measures have been taken to contain movement of livestock within the country.

- **Announcement by EFSA: Opinion on small scale dairy cow farming and welfare issues**

EFSA announced that a public consultation will be launched from 8 December 2014 to 30 January 2015 on an Opinion on small scale dairy cow farming and welfare issues. Opinion was initiated early summer and will potentially be adopted next summer. The document will be available on the EFSA website and stakeholders are invited to provide feedback. (*NOTE:* has been launched since: **http://www.efsa.europa.eu/de/consultations/call/141210.htm**)

6. FAQ document for implementation of animal by-product rules, SANCO G2

The Commission distributed the latest version of the Frequently Asked Questions (FAQ) discussed with Member States. The document will be presented on 15 and 16 December 2014 at the Animal by-Product Working Group. Comments are welcome by 5 December 2014 to include in the text before discussion with Member States at the Working Group. To push on with the compilation, only those questions/answers will remain on the list, which will get the consensus of the MS experts. The document will be published on the Commission website and will remain a living document to which other consensual questions and answers will be gradually added. The Commission informed that the document has been circulated via email on Friday to the mailing list of this group.

EUROGROUP expressed concern on the removal and collection of by-products in mobile slaughterhouses. The Commission informed that there are no restrictions for mobile slaughter and the competent authority is responsible for the collection and storage of ABPs.

FEFAC highlighted the issue of interpretation of data between Member States and the possibility that consensus may not be reached on the Q&A. The Commission informed that EC will try to solve the questions in subsequent turns of discussions with the MS to reach common ground.

FESAS proposed that the document may be available in different languages besides English. The Commission took note and will pass on to hierarchy. Should the final document have a solid base, then the translation would be a good investment.

7. FVO, SANCO F6

– **Overview on EU animal health laboratories**

Stakeholders conveyed appreciation for the presentation delivered. EUROGROUP requested clarification of the word "non-compliant", ATA inquired if the Commission is addressing the issue of laboratories across Member States to be consistent in their analysis of identical tests which at times produce different results. The Commission clarified and confirmed these.

– **Mid-term results of the series on slaughter**

EUROGROUP asked if exemplary countries are compliant with the regulation; questioned whether slaughter without stunning are commercially done properly, given time restrictions if they are to be used; and when will discussions with stakeholders take place. The Commission pointed out that most Member States are in the process of becoming compliant: a sample of 12 Member States has been visited and the Netherlands and Denmark are ahead. As regards slaughter without stunning, the legal basis and constraints are clear we should wait the outcome of the full overview report. The stakeholders will be consulted on the report, details are under discussion. Report is planned to be published next year (tentative April/May) after consultation with Member States. EUROGROUP stressed that it is the Member States that have to comply and deliver and suggested that the Commission may consider that discussions be held jointly between stakeholders and Member States..

FVE highlighted that the BTSF training event scheduled in October 2015 is too far away. The Commission fully recognised the training needs; the programme was initially scheduled in June. Due to contractual constraints it had to be postponed to October.

– **Stakeholder feed-back on FVO reports**

The Commission has taken the initiative to focus on the quality of its reports to ensure that reports are delivered and communicated in a clear and coherent manner and that they meet its customers' expectations. EUROGROUP and AVEC requested clarification as to whom the questionnaire is addressed. The Commission confirmed that the questionnaire is for meeting participants and may be passed on to members within the organisations who may provide valuable feedback. FEFAC asked if the questionnaire would be opened to a wider audience, while the Commission preferred to limit the questionnaire to this forum as a pilot project to receive immediate feedback. A broader consultation may be considered in the long-term.

8. Updates from the Commission on disease situation:

– **African swine fever in the EU,** SANCO G2

Following the presentation, participants were informed that additional measures, technical assistance and training were put in place by the Commission in the region (within and outside

the EU) on specific ASF matters, including: visits in affected Member States providing short training veterinary programmes, and financial support to control the disease.

Following the presentation by the Commission on ASF, the OIE informed on the new GF-TADs (Global Framework for the progressive control of Transboundary Animal Diseases) initiative with the countries in the region focusing on ASF. The kick-off meeting took place in September in Switzerland and the next meeting is scheduled for December in Belarus, the topic for discussion will be wild boar. It is entitled "Regional studying groups of experts on ASF for Eastern European and Baltic Countries", in the framework of GF-TADs (Global Framework for the progressive control of Transboundary Animal Diseases) with the involvement of partners at regional level. The initiative gathers representatives and CVOs of the 7 infected countries from this part of Europe to discuss technical issues on regional strategies with the support of experts. Meetings are held on a monthly/bimonthly basis together with the support of experts OIE, FAO and the EU and identify common strategies on a given topic. The Commission welcomed this initiative and was happy to actively contribute to it in order to foster the dialogue in the region.

- **Foot and mouth disease in North Africa,** SANCO G2 (done before the lunch)

After the presentation the OIE added that it has validated a programme for combatting FMD before first outbreaks for Tunisia, Algeria and Morocco. Despite of these outbreaks the control system is functioning in these countries, indeed effectively as Morocco is not yet affected. A recent REMESA meeting led to the resolution for the set-up of a vaccine bank for FMD. The bank will be established in collaboration with OIE for Maghreb countries and may be extended further. OIE looks forward to collaboration with EU to set-up the bank in an adequate and flexible manner. FESASS expressed its conviction for improvement the situation and appreciated international cooperation in this issue.

9. Any other business

- **Avian Influenza in the EU,** SANCO G2 (done before the lunch)

The Commission informed that 3 weeks ago there was an outbreak of Avian Influenza H5N8 on a turkey farm in Germany –cause of concern being the first outbreak in Europe. (have been known to occur in the Far East: Korea, Japan and China). Member States were fully supportive and reacted immediately. Germany is under control. Approximately 2 weeks after, 2 separate outbreaks in the Netherlands (laying hen farms) and in the UK (a duck farm) took place possibly caused by wild birds: 3 outbreaks occurred in farms close to ponds and lakes where migratory birds stopover. AI was reported in Germany again in a healthy wild duck that was hunted down. The outbreaks in the Netherlands are most concerning due to the presence of vast wetlands and many poultry farms. The Commission is very closely monitoring the situation together with the Member States concerned. Timely information is being dispatched to Member States. Safeguard decisions have been adopted to control outbreak and for transparency reasons. The future is uncertain due to outspread of virus by wild birds. EFSA and EURL are making further analysis. (*NOTE:* add link to EFSA publication Far spread of virus is only 2nd time happening and is concerning. The genetic characteristic of the virus does not show increased affinity for humans, information is still being gathered by scientists. Precautions are being taken for health and safety of workers in contact with infected birds. Outbreaks are not related, showing effectiveness of measures, the Netherlands adopted additional measures too. The Commission is closely monitoring the situation with Member States. Guidelines are available on website. Chief Veterinary Officers will meet tomorrow in Council and PAFF on 28 November and 5 December respectively.

EUROGROUP inquired about preventive measures and vaccination. The Commission informed that, due to high risk, biosecurity enhancement in open air farms is being discussed with stakeholders. It is difficult to draw a balance: there is clear interest to keep birds outside. while they can be better protected indoors. On the other hand we experienced now that the virus has entered farms where poultry was kept indoors. Member States are reviewing their biosecurity measures and discussions are on-going key is not to be surprised at and be prepared for anything. Regarding vaccination, there is no information that any Member State is fully considering vaccination. The vaccination has its limitations: cumbersome and expensive as each animal has to be inoculated twice and the risk is difficult to quantify. EU legal framework and the Commission are flexible and ready to approve programmes. EFSA and EURL are collating data and preparing a risk assessment.

AVEC stressed that measures taken by the Netherlands are very firm but if are not well understood, have the potential to undermine consumer confidence in the products. The Commission confirmed there is no risk for food safety and NL measures are to protect livestock.