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Standing Committee on Plants, Animals, Food and Feed

Section *Animal Nutrition*

19 - 21 April 2021

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SUMMARY REPORT

As mentioned in the invitation to the meeting sent out on 30 March 2021, the meeting was **held via videoconference** due to the situation derived from the COVID-19 pandemic.

The invitation provided relevant information concerning the modalities of the meeting and referred to the use of the written procedure for the delivery of the Committee opinions on the draft implementing acts under Section B of the meeting's agenda.

During the meeting, the following introductory statements were made by a representative of the Commission:

- The confidentiality obligations required by Article 13 of the Standard Rules of Procedure for Committees and referred to in the invitation to the meeting, were recalled.
- The modalities for the delivery of the Committee opinions on the draft acts under Section B of the meeting's agenda by written procedure, were explained.

Section A Information and/or discussion

A.01 Feed Additives - Applications under Regulation (EC) No 1831/2003 - Art. 4, 14 or 13

The relevant documents were sent to the Member States.

A.01.1 An application on the use of cannabidiol as feed additive has been discussed. The Member States' representatives requested more information on the specific use of this product.

A.02 Feed Additives - Applications under Regulation (EC) No 1831/2003 - Art. 9

A.02.01 Safety and efficacy of a feed additive consisting of lasalocid A sodium and nicarbazin (NilablendTM200G) for chickens for fattening (Zoetis Belgium SA)

A discussion was held. The Member States agreed to give the possibility to the applicant to submit supplementary information.

A.02.02 Safety and efficacy of Deccox[®] (decoquinat) for chickens for fattening (2018) / A.02.03 decoquinat (Deccox[®]) for use in chickens for fattening (Zoetis

Belgium SA) (2021) – Annex / A.02.04 Avi-Deccox® 60G (decoquinat) for chickens for fattening – Annex

A discussion was held on a draft Annex document related to both applications. A draft Implementing Regulation will be presented at a future meeting.

A.02.05 proposal of malic acid, citric acid produced by *Aspergillus niger* DSM 25794 or CGMCC 4513/CGMCC 5751 or CICC 40347/CGMCC 5343, sorbic acid and potassium sorbate, acetic acid, sodium diacetate and calcium acetate, propionic acid, sodium propionate, calcium propionate and ammonium propionate, formic acid, sodium formate, calcium formate and ammonium formate, and lactic acid produced by *Bacillus coagulans* (LMG S-26145 or DSM 23965), or *Bacillus smithii* (LMG S-27890) or *Bacillus subtilis* (LMG S-27889) and calcium lactate as feed additives for animal species – Annex

A discussion was held on the draft Annex document. A new draft Annex will be presented at a future meeting.

A.02.06 L-tryptophan produced by E-coli KCCM 80210 for all animal species (FAD-2020-0038) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and a draft Annex entry was presented. A draft authorisation Regulation will be proposed at one of the next Committee meetings.

A.02.07 endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG S-15136 for sows in order to have benefits in piglets and for all porcine species (FAD-2020-0039) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and a draft Annex entry was presented. A draft authorisation Implementing Regulation will be proposed at one of the next Committee meetings.

A.02.08 endo-1,4-beta xylanase produced by *Trichoderma reesei* CBS 114044 for piglets (weaned), chickens reared for laying, chickens for fattening, turkeys for fattening and turkeys reared for breeding for the renewal of its authorisation (FAD-2020-0074) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and a draft Annex entry was presented. A draft authorisation Implementing Regulation will be proposed at one of the next Committee meetings.

A.02.09 serine protease produced by *Bacillus licheniformis* (DSM 19670) for chickens for fattening (FAD-2019-0010) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and a draft Annex entry was presented. A draft authorisation Implementing Regulation will be proposed at one of the next Committee meetings.

A.02.10 muramidase produced by *Trichoderma reesei* DSM 32338 for use in weaned piglets (FAD-2020-0012) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and a draft Annex entry was presented. A draft authorisation Implementing Regulation will be proposed at one of the next Committee meetings.

A.02.11 ferric citrate chelate for suckling and weaned piglets and minor porcine species (FAD-2020-0032) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and a draft Annex entry was presented. A draft authorisation Implementing Regulation will be proposed at one of the next Committee meetings.

A.02.12 Manganese chelate of lysine and glutamic acid (FAD-2020-0026) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and a draft Annex entry was presented. A draft authorisation Implementing Regulation will be proposed at one of the next Committee meetings.

A.02.13 Zinc chelate of Ethylenediamine (ZnEDA) for all animal species (EFSA-Q-2018-00689)

As the EFSA opinion is inconclusive, the Committee agreed to give the possibility to the applicant to compile a dossier with supplementary information in order to allow EFSA to update its opinion.

A.02.14 Manganese chelate of Ethylenediamine (MnEDA) for all animal species (EFSA-Q-2018-00713)

As the EFSA opinion is inconclusive, the Committee agreed to give the possibility to the applicant to compile a dossier with supplementary information in order to allow EFSA to update its opinion.

A.02.15 Assessment of the feed additive consisting of *Enterococcus faecium* DSM 7134 (Bonvital®) for chickens for fattening for the renewal of its authorisation (Lactosan GmbH & Co. KG) - Annex

A discussion was held. A draft Implementing Regulation will be proposed at a future Committee meeting.

A.02.16 Safety and efficacy of the feed additive consisting of *Clostridium butyricum* FERM BP-2789 (Miya-Gold®S) for use in chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), piglets (suckling and weaned) and minor porcine species - Annex

A discussion was held. A draft Implementing Regulation will be proposed at a future Committee meeting.

A.02.17 Safety and efficacy of the feed additive consisting of *Bacillus licheniformis* DSM 28710 (B-Act®) for laying hens, minor poultry species for laying and for breeding purposes and ornamental birds - Annex

A discussion was held. A draft Implementing Regulation will be proposed at a future Committee meeting.

A.02.18 Statement on the safety and efficacy of the feed additive consisting on tragacanth gum for all animal species

A discussion was held. A draft Implementing Regulation denying the authorisation of the additive will be proposed at a future Committee meeting.

A.02.19 Safety and efficacy of feed additives consisting of dried extracts from *Echinacea angustifolia* DC. or *Echinacea purpurea* (L.) Moench for use in cats and dogs

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.20 Safety and efficacy of a feed additive consisting of the seed husk of *Plantago ovata* Forssk. for use in cats and dogs

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.21 Safety and efficacy of a feed additive consisting of a dried extract from *Garcinia gummi-gutta* (L.) Roxb. for use in cats and dogs

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.22 Safety and efficacy of the feed additive consisting of VitaminB2/Riboflavin produced by *Eremothecium ashbyi* CCTCCM 2019833 for all animal species (Hubei Guangji Pharmaceutical Co., Ltd)

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.23 Safety and efficacy of a feed additive consisting on *Ligilactobacillus animalis* ATCC PTA-6750 (formerly *Lactobacillus animalis*) for all animal species(Chr. Hansen A/S)

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.24 Safety and efficacy of a feed additive consisting on *Propionibacterium freudenreichii* ssp. *shermanii* ATTC 5 PTA-6752 for all animal species(Chr. Hansen A/S)

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.25 Safety of 31 flavouring compounds belonging to different chemical groups when used as feed additives for all animal species

The applicant intends to present supplementary information by July 2021 on the safety of beta-damascone, and (E)-beta-damascone for the terrestrial environment. It was agreed to wait for this additional information and to request an opinion to EFSA if the applicant respects the proposed deadline.

A.02.26 Safety and efficacy of an additive consisting of synthetic vitamin K1 (phytomenadione) for horses (JARAZ Enterprises GmbH & Co. KG)

A draft annex entry was discussed with a view to propose a draft authorisation Implementing Regulation concerning this additive at the next Committee meeting.

A.03 Information on the procedure for the electronic submission of applications for the authorisation of feed additives

A presentation on the electronic submission of applications for the authorisation of feed additives was made to the Member States by a representative of EFSA. A short exchange of views took place.

A.04 Information on EU-UK readiness and preparedness as from 1 January 2021

The Member States were invited before the meeting to submit in written form any questions they had relating to actions needed to implement the EU-UK Withdrawal Agreement. The questions submitted were read and answered with the collaboration of Unit G2 of DG SANTE.

A.05 Feed marketing Regulation (EC) No 767/2009

A.05.01 Revision of Regulation (EU) No 68/2013 on the Catalogue of feed materials

The Committee discussed a new version of the draft to revise the Catalogue of feed materials, in particular the hemp entries and algae meal. Progress was made on how to define hemp-derived feed materials as regards their CBD content and on how to address potential health issues as regards feed materials rich in certain trace elements.

As a consequence of the recent Commission Implementing Regulation (EU) 2021/758 on the status of certain products as feed additives within the scope of Regulation (EC) No 1831/2003 and on the withdrawal from the market of certain feed additives, several feed materials should be delisted from the Catalogue, as their feed additive status was clarified. An appropriate transitional period is laid down in Implementing Regulation (EU) 2021/758, in order to allow interested parties to obtain authorisation as feed additives for such products.

Work on the draft will continue at the next Committee meeting.

A.05.02 Revision of Annexes I, II and III

This item was discussed in the margins of item A.05.01.

A.05.03 State of play on applications for feed for particular nutritional purposes

- **New: Reduction of the risk of milk fever and subclinical hypocalcaemia (Phibro)**
- **New: Support of liver function in the case of chronic liver insufficiency cats/dogs (Candioli)**

The Commission's representative informed the Committee that the Commission received the following new applications for feed for particular nutritional purposes:

80: Reduction of the risk of milk fever and subclinical hypocalcaemia (PHIBRO)

81: Support of liver function in the case of chronic liver insufficiency for cats/dogs (Candioli)

82: Stress reactions for equidae (Navalis)

84: Support of cardiac muscle and metabolism in felines with subclinical hypertrophic cardiomyopathy (Royal Canin)

The Member States have been invited to evaluate the respective dossiers, which can be found in Circa BC. Moreover, it has been stressed that supplementary information from the applicant has been uploaded for #77: Reduction of oxalate stones formation.

A.05.04 Discussion of borderline products, including arbitrary entries in the Register of feed materials

- **Magnesium acetate, sodium acetate**

The Committee concluded that magnesium and sodium salts of acetic acid should be considered as feed additives.

- **neem (*Azadirachta indica*)**

The Committee concluded that products derived from *Azadirachta indica* (commonly known as neem, nimtree, indian lilac or margosa), e.g. leaves, bark or cake (co-product of oil extraction from neem seeds), should, due to several [active substances](#), not be considered as feed materials.

A.05.05 Official Controls of added amounts of additives in compound feed

Based on an enquiry of a stakeholder, the Committee discussed three issues:

- Tolerances on the added amount:

The tolerances laid down in Part B of Annex IV of Regulation (EC) No 767/2009 include the technical deviation only; in order to determine the total tolerance, the analytical tolerance (sampling and measurement uncertainty) needs to be added. They shall apply to feed additives in the list of feed additives and in the list of analytical constituents. As regards feed additives listed as analytical constituents, the tolerances shall apply to the total amount labelled.

- Option for feed additives of the functional group “vitamins, pro-vitamins and chemically well-defined substances having similar effect”:

For the mandatory and voluntary indication of the amount of vitamins, pro-vitamins and chemically well-defined substances having similar effect, the responsible feed business operator has the option to label the added amount or the total amount guaranteed during the complete shelf-life. These options are only set for the functional group mentioned above and neither for trace elements, nor for amino acids or antioxidants. The feed business operator may indicate voluntarily both values on the labelling, subject to the condition that this is not misleading, for example if there is a significant discrepancy between the labelled amount and the analysable amount at the moment of the placing on the market.

- Control of added amounts:

The Commission's representative clarified that the added amount is the quantity according to the mixing protocol, which means that losses during the manufacturing procedure cannot be deducted from the labelled added amount.

Concerning the official controls in the field, they fall within the competence of the authorities of the Member State at stake. However, the Commission is ready to advise the national control authorities concerning the meaning of the Regulation in order to ensure a harmonised enforcement throughout the EU.

A.06 RASFF

The Commission representative informed the Committee on the RASFF notifications related to undesirable substances in animal feed, issued since the meeting of the Committee in February 2021.

The notifications related to a too high level/content of:

- aflatoxin B1 (150 µg/kg) in groundnuts from India;
- aflatoxin B1 (122 µg/kg) in sunflower seeds from Egypt;
- aflatoxin B1 (25 µg/kg) in corn gluten from France;

- lead (71.9 mg/kg) in deer chew sticks from Germany;
- fluorine (4500 mg/kg) monocalcium phosphate powder from Turkey;
- ergot sclerotia (5807 mg/kg) in rye from Germany.

Furthermore the attention was drawn to the presence of non-compliant residue level of the pesticide haloxyfop (0.782 mg/kg) in linseeds from Russia, on the presence of the prohibited medicinal product ronidazole (34 µg/kg) in lysine sulphate from China and ethylene oxide in psyllium (husks) and soybean meal from India (most findings in sesame seeds from India).

Following these findings on the presence of ethylene oxide sesame seeds and other products from India, the Commission representative referred to the increased frequency of controls currently in place for the presence of ethylene oxide in sesame seeds from India intended for food ([Commission Regulation \(EU\) 2019/1793 as amended](#)). It is foreseen to extend this provision on increased frequency of controls also to sesame seeds and derived products intended for feed. There are also findings of presence of ethylene oxide in products originating from other countries. No increased frequency of controls have been imposed yet on these products, but an increased vigilance is warranted.

Feed products in which ethylene oxide is present in feed above the MRL (*i.e.* Limit of Quantification) cannot enter the feed chain and has to be disposed of safely. Compound feed with levels of ethylene oxide above the limit of quantification has to be withdrawn from the market. No measures are to be taken as regards animals and products of animal origin from animals, fed with feed that possibly contained ethylene oxide before the contamination of the concerned feed was known.

An extensive exchange of views has taken place on the RASFF notification on the presence of Marigold extract in feed for cats from France, Austria and Poland (RASFF 2021.0902). The use of marigold extract, a lutein-rich extract of *Tagetes erecta*, in feed for cats is a non-authorized use of a feed additive and therefore cat food containing marigold extract is not allowed to be placed on the EU market.

A.07 Undesirable substances

Discussion on foreseen provisions on deoxynivalenol, zearalenone, fumonisins, T-2 and HT-2 toxin and ochratoxin A

An exchange of views has taken place on the outcome of the discussions at the stakeholder forum on mycotoxins in feed that has taken place on 9 March 2021 and the subsequent discussions in the Working group Undesirable substances. Following these discussions, some regulatory levels are proposed to be increased (zearalenone in sugar beet products, T-2 and HT-2 in oats, fumonisins B1+B2 in complete feed for horses and pigs). Before concluding on the approach to be taken, the Commission representative indicated that it is appropriate to have more information on the year-to-year variation and to request the EURL to provide an overview of available analytical methods for the analysis of the different mycotoxins in feed (screening methods and confirmatory methods). Also, there is a need for more detailed and concrete information on the controls that are performed by the feed business operators and competent authorities in the current regulatory framework.

Discussion on provisions on other undesirable substances as discussed at the Working Group Undesirable substances

The Committee was informed on the ongoing discussions as regards nitrates/nitrites, THC, dioxins and dioxin-like PCBs, ergot sclerotia and ergot alkaloids, tropane alkaloids, pyrrolizidine alkaloids, quinolizidine alkaloids, p-phenetidine, lead in game meat and humic acid, arsenic in fishmeal and PFAS.

A.08 Methods of analysis

The Committee was informed of the changes to the Annex of Regulation (EC) No 152/2009 as discussed and agreed at the Working Group Methods of Analysis in Feed. Two main points need to be further discussed in the Working group: the procedure for the macroscopic examination of samples for the presence of ergot sclerotia and botanical impurities and the possible explicit reference to European standards in the Annex to Regulation (EC) No 152/2009 for analytes for which no method of analysis is provided for in the Annex.

Section B Drafts presented for discussion prior to an opinion by written procedure

The documents concerning the items under this section were communicated to the Committee members in advance of the meeting for possible comments.

During the meeting, an exchange of views took place on each of the draft measures referred to under items B.01, B.02, B.03, B.04, B.05 and B.06 in order to reach an agreement on the content of the respective documents.

After the meeting, a final version of the documents resulting from the discussions held during the meeting was sent to the Committee members for possible rectification or editorial comments, with a deadline for reply set on 23 April 2021.

In accordance with Article 3(5) of Regulation (EU) No 182/2011, the **written procedure** for the delivery of the Committee opinion on the six draft Implementing Regulations concerned was launched on 29 April 2021 with a deadline set on 5 May 2021.

Member States representatives were informed on the outcome of the written procedure by a note sent on 7 May 2021. The Committee opinion delivered on each draft measure is mentioned below in relation to items B.01, B.02, B.03, B.04, B.05 and B.06.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation suspending the authorisation of lasalocid A sodium (Avatec 15% cc) and lasalocid A sodium (Avatec 150 G) as feed additives for chickens for fattening and chickens reared for laying (holder of authorisation Zoetis Belgium S.A.)

The draft refers to the suspension of the authorisation of lasalocid A sodium (Avatec 15% cc) and lasalocid A sodium (Avatec 150 G) as additives belonging to the category of coccidiostats and histomonostats, for use for chickens for fattening and chickens reared for laying.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species, and repealing Regulation (EU) No 350/2010

The draft refers to the renewal of the authorisation of an amino acid as feed additive.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of the authorisation of zinc chelate of hydroxy analogue of methionine as feed additive for all animal species, and repealing Regulation (EU) No 335/2010

The draft refers to the renewal of the authorisation of an amino acid as feed additive.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of L-threonine produced by *Escherichia coli* CGMCC 13325 as a feed additive for all animal species

The draft refers to the authorisation of an amino acid as feed additive.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404 as a feed additive for poultry species, ornamental birds and weaned piglets (holder of the authorisation: BASF SE), and repealing Regulation (EC) No 271/2009 and Implementing Regulation (EU) No 1068/2011

The draft refers to the renewal of the authorisation of a zootechnical feed additive.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of the authorisation of a preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 as a feed additive for pigs and poultry (holder of the authorisation: Roal Oy), and repealing Regulations (EU) No 277/2010, (EU) No 891/2010 and Implementing Regulation (EU) No 886/2011

The draft refers to the renewal of the authorisation of a zootechnical feed additive.

Vote taken: Favourable opinion.

M.01 Open Public Consultation on Impact assessment of the feed additives Regulation

The Commission's representative informed the Committee on the Open Public Consultation on Impact assessment of the feed additives Regulation that was launched. The information on how to participate in the consultation was given to the Member States' delegations with the request to disseminate this information within their respective countries.

M.02 Safety and efficacy of COXAM® (amprolium hydrochloride) for chickens for fattening and chickens reared for laying (2018) (2021) - Annex

A discussion was held on a draft Annex document. A draft Implementing Regulation will be presented at a future Committee meeting.