EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2020)8528476

Standing Committee on Plants, Animals, Food and Feed

Section *Animal Nutrition*

12 - 13 November 2020

CIRCABC Link: ***https://circabc.europa.eu/w/browse/bed10bc1-b8ab-44dd-894a-4a767c423329***

SUMMARY REPORT

As mentioned in the invitation to the meeting (ref. Ares(2020)6103771 of 29/10/2020), the Committee meeting was **held via Web Conferencing (WebEx)** due to the COVID-19 pandemic.

The invitation provided relevant information concerning the modalities of the WebEx 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.

Documents were sent to the Member States.

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

A.02.01 Denial of authorisation of phosphoric acid 60% on silica carrier as a feed additive belonging to the functional group of binders

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

A.02.02 Safety and efficacy of Bonvital® (*Enterococcus faecium* DSM 7134) as a feed additive for laying hens

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

A.02.03 Assessment of the application for renewal of the authorisation of Calsporin® (*Bacillus velezensis* DSM 15544) as a feed additive for weaned piglets

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

A.02.04 Safety and efficacy of CorrelinkTM ABS747 *Bacillus subtilis* (*Bacillus velezensis* NRRL B-67257) as a feed additive for all growing poultry species

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

A.02.05 Safety and efficacy of CorrelinkTM ABS1781 *Bacillus subtilis* (*Bacillus velezensis* NRRL B-67259) as a feed additive for all growing poultry species

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

A.02.06 Safety and efficacy of *Bacillus subtilis* PB6 (*Bacillus velezensis* ATCC PTA-6737) as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species (except for laying purposes), ornamental, sporting and game birds

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

A.02.07 Assessment of the application for renewal of authorisation of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) as a feed additive for weaned piglets

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

A.02.08 Assessment of the application for renewal of authorisation of pyridoxine hydrochloride (vitamin B6) as a feed additive for all animal species

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

A.02.09 Safety of methanethiol when used as a feed additive for all animal species

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

A.02.10 Safety and efficacy of turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from Curcuma longa L. rhizome when used as sensory additives in feed for all animal species

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

A.02.11 Safety and efficacy of essential oil, oleoresin and tincture from Zingiber officinale Roscoe when used as sensory additives in feed for all animal species

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

A.02.12 Natural essential oil from *Origanum vulgare* L. *ssp. hirtum* var. Vulkan (DOS 00001), when used as a feed additive for all animal species under the conditions of Regulation (EC) No 1831/2003 F AD- 2016-0004 - FAD-2019-0018 - Supplementary information

A discussion took place on the letter concerning complementary information submitted by the applicant. The discussion will continue at the next Committee meeting.

A.02.13 L-histidine monohydrochloride monohydrate produced by *Escherichia coli* KCCM 80212 as a feed additive for all animal species (FAD-2020-0016) - Annex entry

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

A.02.14 L-valine produced by *Corynebacterium glutamicum* CGMCC 7.358 as a feed additive for all animal species (FAD-2019-0072) - Annex entry

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

A.02.15 L-lysine monohydrochloride and concentrated liquid L-lysine (base) produced by *Corynebacterium casei* KCCM 80190 as feed additives for all animal species (FAD-2019-0014) - Annex entry

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

A.02.16 Manganese chelate of hydroxy analogue of methionine for all animal species (FAD-2019-0032) - Annex entry

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

A.02.17 6-phytase produced by *Komagataella phaffii* CGMCC 7.19 for chickens for fattening, other poultry for fattening, reared for laying and ornamental birds (FAD-2019-0005)

As the EFSA opinion is inconclusive, the Committee agreed to allow the applicant to compile a dossier with supplementary information to allow EFSA an update of the opinion.

A.02.18 Safety and efficacy of Avatec® 150G (lasalocid A sodium) as a feed additive for chickens for fattening and chickens reared for laying. Update

A discussion was held on two options to withdraw the product from the market. In agreement with the Member States, a suspension of the authorisation of this coccidiostat for chickens for fattening and chickens reared for laying will be proposed at a future meeting.

A.02.19 Safety and efficacy of DSP® (Na2EDTA, tannin-rich extract of Castanea sativa, thyme oil and origanum oil) for pigs for fattening. Update

A discussion was held. In agreement with the Member States, supplementary information will be requested to complete the assessment.

A.02.20 Safety and efficacy of STABILFLOR® as a zootechnical feed additive for pigs for fattening. Update

A discussion was held. Since no conclusions have been reached, in particular on the classification of this product, a new discussion will take place at a future meeting.

A.03 Draft Commission Implementing Regulation on the status of certain products as feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council and on the withdrawal from the market of certain feed additives: information on last version of the draft measure

A representative of the Commission presented the last version of the document, for which internal consultation procedures are still ongoing. In particular, the motivation (recitals) of the envisaged draft act is being reviewed. A short discussion took place. A

revised version of the document will be transmitted to the Committee at its next meeting.

A.04 Feed marketing Regulation (EC) No 767/2009

A.04.01 Revision of Regulation 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, algae meal and the new structure of Chapter 12. Several Member States delegates suggested to include certain feed materials in Annex III of Regulation (EC) No 767/2009 with prohibited and restricted materials. On several issues, the Commission will seek clarification from the Feed Chain task force. A revised draft of the Catalogue will be presented at the next Committee meeting.

A.04.02 Discussion of borderline products, including arbitrary entries in the Register of feed materials:

RNA

A manufacturer of such a product presented supplementary information about the manufacturing procedure, its nutritional value and functionality in animal nutrition. Considering this information and all other information available, the Committee concluded to classify it as yeast product as listed in the Catalogue of feed materials (entry 12.1.12). As regards the name of the feed material, the Committee advised the following: „Product rich in ribonucleic acids obtained from yeast cultured from paper industry“.

A.04.03 State of play on ParNut applications and errors in Regulation 2020/354

The Commission's representative invited the Member States to convey consolidated lists with translation errors in Regulation 2020/354, as appropriate. No news on pending applications.

A.04.04 Eligibility of specifically formulated feed, e.g. without animal products, for certain target species, e.g. carnivores.

A discussion took place about the eligibility of feed without animal products for carnivores. Article 4 of Regulation (EC) No 767/2009 requires that feed shall be safe, sound, genuine, unadulterated, fit for its purpose and of merchantable quality. Moreover, Article 11 stipulates that labelling of feed shall not be misleading.

A priori, it cannot be assumed that a feed without animal products placed as complete feed for dogs on the market is unsafe or not fit for its purpose. However, it is up to the feed business operator placing the feed on the market to ensure that the respective feed complies with the definition of “complete feed” in Article 3 and the requirements in Article 4, and that its labelling is truthful.

A.05 Placing on the EU market of complementary feed containing nutritional feed additives which are not authorised for use in water for drinking

As a follow up of the discussion in the SCoPAFF meeting of September 2019, the eligibility of the different routes of administration of nutritional feed additives, which are not authorised for use in water for drinking, was discussed. The Commission's representative expressed that, especially for feed additives with a maximum level, the different sources of the exposure with the additive need to be taken into account. As the

stakeholders announced to develop a calculation tool for this issue, the Committee will come back to the discussion once this tool is available.

A.06 Information point on the electronic submission of applications for the authorisation of feed additives

An introductory presentation on the future electronic submission of applications for the authorisation of feed additives was made to the Member States by a Commission's representative. A short exchange of views took place.

A.07 Information point 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. A Commission's representative updated the Member States on the state of negotiations and invited the Member States to present any questions that may arise at the next Committee meeting, where the information point will be put again on the agenda.

A.08 RASFF

Update and exchange of views on:

- RASFF 2020.4244: finding of zilpaterol in sugar cane molasse from South Africa:

The Irish delegation provided extensive information on the actions and measures taken as regards the finding of zilpaterol in sugar cane molasses from South Africa.

Following the finding of residues of zilpaterol in the urine of race horses, the contamination could be traced back to the presence of zilpaterol in sugar cane molasses from South Africa. All possibly affected feed has been traced and recalled from the market ensuring a high level of feed safety. As regards the source of contamination of the sugar cane molasses with zilpaterol, investigations are ongoing and the authorities from South Africa have been contacted.

- Other recent RASFF notifications:

The Commission's representative informed the Committee on the RASFF notifications related to undesirable substances in animal feed, issued since the meeting of the Committee in September 2020.

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

- aflatoxin B1 in groundnut kernels from India (211 µg/kg), US (63.3 µg/kg) and Argentina 56.1 µg/kg);

- arsenic (6.5 mg/kg), cadmium (0.95 mg/kg) and lead (18 (mg/kg) in complementary feed for piglets from Belgium;

- arsenic (13.4 mg/kg) in mineral feed from Netherlands;

- arsenic (2.9 mg/kg) in dried algae from China;

- arsenic (42.4 mg/kg) and cadmium (3.16 mg/kg cadmium) in complementary feed for dogs from Germany (raw material from Chile and Ireland);

- amoxicillin (> 2 mg/kg) in complete feed for piglets from UK;

- lasalocid (11.6 mg/kg) in complete feed for turkeys from Poland;

- narasin (10 000 ppm) and of nicarbazin (23 000 ppm) in turkey feed premix from Belgium;

- chlorpyrifos (0.35 mg/kg) in rapeseed meal from Poland;

- haloxyfop (0.032 mg/kg) in linseeds from Russia;

- bromuconazole (0.035 mg/kg) in barley from Poland.

Furthermore the attention was of the unauthorised placing on the market of the feed additive Iron (II) sulphate monohydrate produced by a company in Poland from iron sulphate imported from Ukraine marketed for purposes other than feed. The Polish authorities have taken the necessary measures to end these illegal practices. There is no indication that this illegal practice would have resulted in a risk for animal or public health.

There were furthermore 3 notifications of dried beet pulp from Ukraine infested with moulds.

A delegation raised the issue of RASFF notifications related to the presence of ethylene oxide in sesame seeds from India, the provisions provided for in Commission Implementing Regulation (EU) 2020/1540 of 22 October 2020 amending Implementing Regulation (EU) 2019/1793 as regards sesamum seeds originating in India and the relevance for feed. The Commission's representative acknowledged that the Implementing Regulation refers to *sesamum* seeds as food and that *sesamum* seeds and derived products could also be used in feed and in case of finding of unacceptable levels of ethylene oxide in *sesamum* seeds and derived products intended for feed, measures have to be taken to ensure a high level of animal health protection.

A.09 Undesirable substances

- Exchange of views on foreseen amendments to the provisions on deoxynivalenol, zearalenone, fumonisins, T-2 and HT-2 toxin and ochratoxin A in view of a possible targeted stakeholder consultation.

The approach for the Regulation on mycotoxins (deoxynivalenol, zearalenone, fumonisins, T-2 and HT-2 toxin and ochratoxin A) in feed as discussed in the Working Group on 06/11/2020 was presented for discussion.

For feed materials, it is suggested to establish guidance levels in a Commission Recommendation, based on the available occurrence data according to As Low As Reasonably Achievable (ALARA), and taking into account the year-to-year variation, climate change, the large variety of feed materials, etc…

For complete feed, it is suggested to establish maximum levels in the frame of the Directive 2002/32/EC on undesirable substances in feed, taking into account the reference point for adverse animal health effect (NOAEL/LOAEL)). In case the current guidance level as established in Commission Recommendation 2006/576/EC is below the level reflecting the reference point for adverse animal health effect and there has been no problem as regards compliance with the current guidance level for the past 15 years, it might be appropriate in certain cases to establish the maximum level not at the level reflecting the reference point for adverse animal health effect, but lower (but in any case not lower than the current guidance level) as it is important to ensure that prevention measures/good practices continue to be applied by all operators in the feed chain.

For complementary feed, no specific levels are suggested to be established and article 6 of Directive 2002/32/EC on undesirable substances would be applicable: "*Insofar as there are no special provisions for complementary feed, Member States shall prescribe that complementary feed may not, taking into account the proportion prescribed for their use in a daily ration, contain level of the undesirable substances listed in Annex I that exceed those fixed for complete feed."* It could be foreseen in the Recommendation that, whenever appropriate, examinations/investigations could be performed in case the complementary feed contains a level of the mycotoxin higher than the maximum level for complete feed but the level is below the maximum level for complete feed when the proportion in a daily ration is taken into account.

Comments were received and discussed on the approach and on some specific provisions related to ochratoxin A. EFSA needs to be consulted on the reference point for adverse health effects for horses and poultry other than laying hens and to update the opinion on ochratoxin A as undesirable substance in feed. The Committee agreed to perform a targeted stakeholder consultation and then considering the comments received from the stakeholders continue the discussion on the approach and the specific provisions.

- Exchange of views on other issues (to be specified)

The Committee was informed on the discussions in the meeting of the Working Group Undesirable Substances that took place on 9 October 2020.

- nickel: no further comments were received on the conclusion at last meeting of the Committee as regards nickel, i.e. a to establish a maximum level of 20 ppm for nickel in fatty acid products and (crude) glycerine) in the frame of Directive 2002/32/EC and not to set maximum levels for nickel in minerals and derived products and in feed additives belonging to the functional group of trace elements and binders and anticaking agents (including mycotoxins and binders);

- ergot sclerotia: the possible lowering of maximum level for ergot sclerotia in unground cereals from to current 1000 mg/kg to 500 mg/kg;

- dioxins and dioxin-like PCBs: given the foreseen timing of the review of the toxic equivalence factors (TEF) by WHO (starting the review of the TEF values in the course of 2021 with the aim to finalise the review by end of 2022), the comprehensive review of maximum levels/action levels to be postponed to 2023. In the meantime, limited review of certain maximum levels / action levels based on current TEF values;

- cadmium in copper (I) oxide: possible increase of maximum level of 10 mg/kg to 15 mg/kg taking into account the provided data;

- glycoalkaloids: reference is made to the EFSA opinion (http://www.efsa.europa.eu/en/efsajournal/pub/6222): Taking into account the outcome of the opinion as regards risks for animal health, no regulatory follow up for glycoalkaloids in feed is proposed for the time being.
The Committee was also informed of the discussion that took place in the meeting of the working group on ergot alkaloids, p-phenetidine, lead in game meat, tropane alkaloids and perfluoralkyl substances (PFAS). These issues need further discussion at the next meeting of the working group (early 2021). At that meeting also EFSA's risk assessment on nitrate and nitrite in feed will be presented and the possible regulatory follow-up will be discussed.

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 11 draft measures in order to reach an agreement on the content of the respective documents. However, as indicated during the meeting, the Committee's opinions on the draft acts referred to under items B.06, B.07, B.08 and B.09 of the agenda will be sought at a later stage, after completion of preliminary internal procedural requirements.
After the meeting, a final version of the documents resulting from the discussions held during the meeting, related to items B.01, B.02, B.03, B.04, B.05, B.10 and B.11, was sent to the Committee members for possible rectification or editorial comments, with a deadline for reply set on 18 November 2020.

In accordance with Article 3(5) of Regulation (EU) No 182/2011, the **written procedure** for the delivery of the Committee opinion on the 7 draft Implementing Regulations concerned was launched on 19 November 2020 with a deadline set on 26 November 2020.
Member States representatives were informed on the outcome of the written procedure by a note sent on 27 November 2020. 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, B.10 and B.11.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of sorbitan monolaurate as a feed additive for all animal species

The draft refers to the authorisation of sorbitan monolaurate as a feed additive for all animal species.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of *Lactobacillus buchneri* DSM 29026 as a feed additive for all animal species

The draft refers to the authorisation of a preparation of *Lactobacillus buchneri* DSM 29026 as a feed additive for all animal species.

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 a preparation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for calves for rearing (holder of authorisation S.I. Lesaffre)

The draft refers to the renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for calves for rearing.

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 a preparation of fumonisin esterase produced by *Komagataella phaffii* DSM 32159 as a feed additive for all animal species

The draft refers to the authorisation of a preparation of fumonisin esterase produced by *Komagataella phaffii* DSM 32159 as a feed additive for all animal species.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of *Lactobacillus parafarraginis* DSM 32962 as a feed additive for all animal species

The draft refers to the authorisation of a preparation of *Lactobacillus parafarraginis* DSM 32962 as a feed additive for all animal species.

Vote taken: Favourable opinion.

B.06 Corrigendum to Commission Implementing Regulation (EU) 2020/1092 of 24 July 2020 amending Implementing Regulation (EU) No 1263/2011 as regards the authorisation of *Lactococcus lactis* (NCIMB 30160) as a feed additive for all animal species

The draft aims at correcting Implementing Regulation (EU) No 1263/2011, as amended by Implementing Regulation (EU) 2020/1092, concerning the authorisation period of *Lactococcus lactis* (NCIMB 30160) as a feed additive for all animal species.

Vote Postponed

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of tincture derived from *Artemisia vulgaris L.* (mugwort tincture) as a feed additive for all animal species

The draft refers to the authorisation of a tincture derived from *Artemisia vulgaris* L. (mugwort tincture) as a feed additive for all animal species.

Vote Postponed

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) correcting Implementing Regulation (EU) 2020/1097 concerning the authorisation of lutein-rich and lutein/zeaxanthin extracts from Tagetes erecta as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying

The draft aims at correcting several elements included in the Annex to Implementing Regulation (EU) 2020/1097.

Vote Postponed

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation extending the suspension of the authorisation of ethoxyquin as a feed additive for all animal species and categories

The draft refers to the extension of the suspension of the authorisation of the additive ethoxyquin and the postponement of the review of Implementing Regulation (EU) 2017/962.

A revised version of the document will be submitted to the Committee at its next meeting.

Vote Postponed

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of 3-phytase produced by *Komagataella phaffii* CECT 13094 as a feed additive for pigs for fattening, minor porcine species, turkeys for fattening and reared for breeding (holder of authorisation: Fertinagro Biotech S.L.)

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

Vote taken: Favourable opinion.

B.11 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 and endo-1,3(4)-beta-glucanase for chickens for fattening (holder of the authorisation AVEVE NV), and repealing Regulation (EC) No 1091/2009

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

Vote taken: Favourable opinion.