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Standing Committee on Plants, Animals, Food and Feed Section Animal Nutrition 01 - 02 April 2020

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SUMMARY REPORT

As mentioned in the invitation to the meeting sent out on 13 March 2020 and in the message sent to the Committee members on 19 March 2020, the meeting was **held via Web Conferencing (WebEx)** due to the situation regarding the outbreak of the COVID-19 virus. The meeting finally took place on 1 and 2 April 2020.

The communications of 13 and 19 March 2020, as complemented in particular by a message sent on 26 March 2020, provided relevant information concerning the modalities of the WebEx meeting and the envisaged delivery of the Committee opinions on the draft measures referred to under Section B of the meeting's agenda through a written procedure, in accordance with Article 3(5) of Regulation (EU) No 182/2011.

In addition, it was specified that the meeting would focus on the following essential agenda's items only: A.02, A.03 and items under Section B, for discussion in view of preparing the subsequent delivery of the Committee opinions via written procedure.

Item A.04 of the agenda was also shortly presented and discussed in the course of the meeting.

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

- The confidentiality obligations required by Article 13 of the Rules of Procedure for the Standing Committee and specified in the communications of 13 and 19 March 2020 to the Committee members, 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. In particular, the aim of the meeting was to have an exchange of views on those draft measures in order to reach an agreement before the launch of the written procedure, after the meeting, for the delivery of the Committee opinions.

Section A Information and/or discussion

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

Documents were sent to the Member States.

- A.02 Feed Additives Applications under Regulation (EC) No 1831/2003 Art. 9
 - A.02.01. Assessment of the application for renewal of authorisation of Formi LHS (potassium diformate) for sows

Supplementary information will be requested to the applicant to complete the evaluation.

A.02.02. Assessment of the application for renewal of the authorisation of Amaferm® (fermentation product of Aspergillus oryzae NRRL 458) as a feed additive for dairy cows

Supplementary information will be requested to the applicant to complete the evaluation.

A.02.03. EB15 10 (Bacillus subtilis DSM 25841) as a feed additive for weaned piglets and weaned minor porcine species – Annex

A new draft Annex will be proposed at a future meeting.

A.02.04. EB15 10 (Bacillus subtilis DSM 25841) as a feed additive for piglets (suckling and weaned), pigs for fattening, sows in order to have benefits in piglets, sows for reproduction and minor porcine specie - Annex

A new draft Annex will be propose at a future meeting.

A.02.05. ZM16 10 (Bacillus amyloliquefaciens DSM 25840) as a feed additive for sows in order to have benefits in piglets, sows for reproduction, piglets (suckling and weaned), pigs for fattening and minor porcine specie – Annex

A draft Regulation will be proposed at a future meeting. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.06. ZM16 10 (Bacillus amyloliquefaciens DSM 25840) as a feed additive for weaned piglets and minor porcine specie – Annex

A draft Regulation will be proposed at a future meeting.

A.02.07. Availa®Cr (chromium chelate of DL-methionine) as a feed additive for dairy cows

Supplementary information will be requested to the applicant to complete the evaluation.

A.02.08. Belfeed B MP/ML (endo-1,4-b-xylanase) as a feed additive for sows, in order to have benefits in piglets, and for all porcine species – Annex

A new draft Annex will be proposed at a future meeting.

A.02.09. Assessment of the application for renewal of authorisation of Yea-Sacc® (Saccharomyces cerevisiae) for horses – Annex

A draft Regulation will be proposed at a future meeting.

A.02.10. Lancer ${\mathbb R}$ (lanthanide citrate) as a zootechnical additive for weaned piglets – Annex

A new draft Annex will be proposed at a future meeting.

A.02.11. Assessment of the application for renewal of authorisation of Ecobiol® (*Bacillus amyloliquefaciens* CECT 5940) as a feed additive for chickens for fattening and its extension of use for chickens reared for laying - Annex

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

A.02.12. L-lysine monohydrochloride and L-lysine sulfate produced using *Corynebacterium glutamicum* CGMCC 7.266 (EFSA-Q-2018-00427) - Annex entry

The EFSA opinion was discussed which concluded that the additives are safe and efficacious. A draft authorisation Regulation will be prepared for vote in one of the next Committees.

A.02.13. L-tryptophan produced by fermentation using *Escherichia coli* CGMCC 7.267 for all animal species (EFSA-Q-2017-00610) - Annex entry

The EFSA opinion was discussed which concluded that the additive is safe and efficacious. A draft authorisation Regulation will be prepared for vote in one of the next Committees.

A.02.14. L-cystine produced using *Pantoea ananatis* NITE BP-02525 for all animal species (EFSA-Q-2019-00332) - Annex entry

The EFSA opinion was discussed which concluded that the additive is safe and efficacious. A draft authorisation Regulation will be prepared for vote in one of the next Committees.

A.02.15. Renewal of authorisation of L-isoleucine produced by *Escherichia coli* FERM ABP-10641 as a nutritional additive, its extension of use in water for drinking and a new use as flavouring additive for all animal species (EFSA-Q-2019-00361) - Annex entry

The EFSA opinion was discussed which concluded that the additive is safe and efficacious. A draft authorisation Regulation will be prepared for vote in one of the next Committees.

A.02.16. L-isoleucine produced by fermentation with *Corynebacterium glutamicum* KCCM 80189 for all animal species (EFSA-Q-2019-00293) - Annex entry

The EFSA opinion was discussed which concluded that the additive is safe and efficacious. A draft authorisation Regulation will be prepared for vote in one of the next Committees.

A.02.17. Endo-1,4-beta-xylanase and endo-1,4-beta-glucanase as a feed additive for sows (EFSA-Q-2017-00651) - Annex entry

The EFSA opinion was discussed which concluded that the additive is safe for sows but could not conclude that it is efficacious for gestating sows. The applicant meanwhile withdrew the application for gestating sows. A draft authorisation Regulation will be prepared for lactating sows for vote in one of the next Committees.

A.02.18. Endo-1,4-betaxylanase, subtilisin and alpha-amylase for all poultry species (EFSA-Q-2018-01040)

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

A.02.19. Essential oil from Origanum 1 vulgare ssp. hirtum (Link) Ietsw. for all animal species - Annex entry

This point was not discussed.

A.02.20. Essential oil from Origanum vulgare subsp. hirtum (Link) letsw. var. Vulkan (DOS 00001) when used as a sensory additive in feed for all animal species - Annex entry

This point was not discussed.

A.02.21. 4-phenylbut-3-en-2-one and benzophenone belonging to chemical group 21 when used as flavouring compounds for all animal species

It was agreed to send a letter to the applicant to request complementary information in case that they do not agree with the EFSA opinion.

A.02.22. Dried aqueous ethanol extract of eaves from Olea europaea L. when used as a sensory additive in feed for all animal species

It was agreed to send a letter to the applicant to request complementary information.

A.02.23. Dried aqueous ethanol extract of Melissa officinalis L. leaves when used as a sensory additive for all animal species

It was agreed to send a letter to the applicant to request complementary information.

A.02.24. Saponified paprika extract, containing capsanthin as main carotenoid source, for poultry for fattening and laying (except turkeys)

The opinion was favourable. A draft Annex entry will be presented at the next Committee.

A.02.25. Ethyl ester of β -apo-8'-carotenoic acid as a feed additive for chickens for fattening, laying hens and minor poultry species for laying and for fattening - Annex entry

The opinion was favourable. A draft Annex entry will be presented at the next Committee.

A.02.26. Lignosulfonate – Annex

A discussion was held. After the last EFSA Opinion, Member States requested to provide an additional period of time to the applicant in order to supply new data regarding the safety of the additive in salmonids and dairy cows.

A.02.27. Hexamethylene tetramine

A Commission's representative explained that the applicant has withdrawn the application of this dossier.

A.02.28. Polyoxyethylene (20)-sorbitan monooleate - E 433

A discussion was held. A Commission's representative explained that the applicant has not submitted data by the agreed deadline in order to finalise the assessment of the additive by EFSA. A majority of Member States indicated not to provide an additional period of time to submit the data, therefore, Commission will proceed accordingly.

A.03 Discussion on amending Regulation (EC) No 429/2008

An outline of the amendment of Regulation (EC) No 429/2008 in accordance with Regulation (EU) 2019/1381 (The Transparency Regulation) was presented to the Member States. A short exchange of views took place.

A.04 Feed marketing Regulation (EC) N° 767/2009

A.04.01. Revision of Regulation 68/2013 on the Catalogue of feed materials

A new version of the revised Catalogue was distributed to the Member States for consideration. The point will be resumed in the next Committee.

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

This item was not discussed.

A.04.03. Corrections in the FEDIAF Code of Good Labelling Practice for Pet Food

A list of corrections in the Code of Good Labelling Practice for Pet Food prepared by FEDIAF was distributed to the Member States who were asked to comment by email within one month. The reactions from the Committee will successively be forwarded to FEDIAF.

A.05 Guides to good practice

The item was not discussed.

A.06 RASFF

The item was not discussed.

A.07 Undesirable substances

The item was not discussed.

A.08 Review of Regulation (EU) 152/2009

The item was not discussed.

A.09 Situation of "COMMISSION DIRECTIVE 98/68/EC of 10 September 1998 laying down the standard document referred to in Article 9(1) of Council Directive 95/53/EC and certain rules for checks at the introduction into the Community of feedingstuffs from third countries" and the enforcement of the new rules of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products

The item was not discussed.

Section B <u>Draft(s)</u> 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 20 draft measures 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 14 April 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 20 draft Implementing Regulations was launched on 17 April 2020 with a deadline set on 24 April 2020.

Member States representatives were informed on the outcome of the written procedure by notes sent on 29 April and on 5 May 2020. The Committee opinion delivered on each draft measure is mentioned below in relation to items B.01 to B.20

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of 6-phytase, produced by Aspergillus niger (DSM 25770) as feed additive for laying hens and minor poultry and other avian species for laying (holder of the authorisation BASF SE)

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

Vote taken by written procedure: 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 endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (BCCM/MUCL 49755) as a feed additive for all avian species for fattening other than turkeys and chickens for fattening and all weaned porcine species and for fattening other than weaned piglets and pigs for fattening (holder of authorisation Berg und Schmidt GmbH Co. KG)

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

The German delegation made the following declaration:

"Die deutsche Delegation kann den Verordnungsvorschlag der Kommission nicht unterstützen, da für die Tierkategorie Masttruthühner keine bewertbaren Daten zur Sicherheit und Wirksamkeit gemäß den Vorgaben der Verordnung (EG) Nr. 429/2008 vorliegen."

Vote taken by written procedure: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by produced by Aspergillus oryzae (DSM 26372) as a feed additive for lactating sows (holder of authorisation DSM Nutritional Products Sp. z 0.0.)

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

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of the preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species reared for laying (holder of authorisation Biomin GmbH)

The draft refers to the authorisation of a preparation of flavourings as zootechnical additive.

Vote taken by written procedure: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of the preparation of Bacillus subtilis DSM 28343 as a feed additive for calves for rearing and pigs for fattening (holder of authorisation Lactosan GmbH & Co. KG)

The draft refers to the authorisation of a microorganism as feed additive.

Vote taken by written procedure: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by Aspergillus oryzae (DSM 26372) as a feed additive for laying hens (holder of authorisation DSM Nutritional Products Sp. z o.o.)

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

Vote taken by written procedure: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of the authorisation of the preparation Saccharomyces cerevisiae MUCL 39885 as a feed additive for sows and repealing Regulation (EC) No 896/2009 (holder of authorisation Prosol SpA)

The draft refers to the renewal of a microorganism as feed additive.

Vote taken by written procedure: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of the authorisation of Saccharomyces cerevisiae MUCL 39885 as a feed additive for dairy cows and horses and repealing Regulation (EC) No 1119/2010 (holder of authorisation Prosol SpA)

The draft refers to the renewal of a microorganism as feed additive.

Vote taken by written procedure: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of benzoic acid as a feed additive for pigs for fattening (holder of authorisation DSM Nutritional Products Sp. z o. o.)

The draft refers to the renewal of a benzoic acid as feed additive.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of monensin and nicarbazin (Monimax) as a feed additive for turkeys for fattening, chickens for fattening and chickens reared for laying (holder of authorisation Huvepharma NV)

The draft refers to the authorisation of coccidiostats as feed additive.

Vote taken by written procedure: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the authorisation of L-histidine monohydrochloride monohydrate as a feed additive for all animal species

The draft concerns the authorisation of L-histidine monohydrochloride monohydrate as amino acid.

Vote taken by written procedure: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of L-threonine as a feed additive for all animal species

The draft concerns the authorisation of L-threonine as amino acid.

Vote taken by written procedure: Favourable opinion.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of the authorisation of Larginine produced by Corynebacterium glutamicum ATCC 13870 and the authorisation of Larginine produced by Corynebacterium glutamicum KCCM 80182 as feed additives for all animal species and repealing Regulation (EC) No 1139/2007

The draft concerns the renewal of the authorisation of L-arginine produced by *Corynebacterium glutamicum* ATCC 13870 and the authorisation of L-arginine produced by *Corynebacterium glutamicum* KCCM 80182 as amino acid and flavouring.

Vote taken by written procedure: Favourable opinion.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of L-lysine monohydrochloride, L-lysine sulfate and concentrated liquid L-lysine (base) as feed additives for all animal species

The draft concerns the authorisation of L-lysine monohydrochloride, L-lysine sulfate and concentrated liquid L-lysine (base) as amino acids.

B.15 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the authorisation of lutein and lutein/zeaxanthin extracts from Tagetes erecta as feed additives for some poultry animal categories

The draft authorises a colourant for some poultry categories.

Vote taken by written procedure: Favourable opinion.

B.16 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation of Escherichia coli KCCM 80180 and Escherichia coli KCCM 80181 as a feed additive for all animal species

The draft authorises a flavouring for all animal species.

Vote taken by written procedure: Favourable opinion.

B.17 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the authorisation of cardamom essential oil from Elettaria cardamomum (L.) Maton as a feed additive for all animal species

The draft authorises a plant extract as a flavouring for all animal species.

Vote taken by written procedure: Favourable opinion.

B.18 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of the authorisation of astaxanthin dimethyldisuccinate as a feed additive for fish and crustaceans and repealing Regulation (EC) No 393/2008 of 30 April 2008 concerning the authorisation of astaxanthin dimethyldisuccinate as a feed additive

The draft authorises a colourant for fish and crustaceans.

Vote taken by written procedure: Favourable opinion.

B.19 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending implementing Regulation (EU) No 1263/2011 of 5 December 2011 concerning the authorisation of Lactobacillus buchneri (DSM 16774), Lactobacillus buchneri (DSM 12856), Lactobacillus paracasei (DSM 16245), Lactobacillus paracasei (DSM 16773), Lactobacillus plantarum (DSM 12836), Lactobacillus plantarum (DSM 12837), Lactobacillus brevis (DSM 12835), Lactobacillus rhamnosus (NCIMB 30121), Lactococcus lactis (DSM 11037), Lactococcus lactis (NCIMB 30160), Pediococcus acidilactici (DSM 16243) and Pediococcus pentosaceus (DSM 12834) as feed additives for all animal species

The draft refers to the proposed modification of the terms of authorisation regarding the formulation of the additive *Lactococcus lactis* NCIMB 30160. The applicant has proposed to modify the manufacturing process by adding polyethylene glycol (PEG 4000) in the list of potential cryoprotectants that can be used.

B.20 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of the preparation of Saccharomyces cerevisiae NCYC R404 as a feed additive for dairy cows

The draft concerns the modification of the representative of the authorisation holder for the additive.

Vote taken by written procedure: Favourable opinion.

M.01 Exchange of letters between the European Association of Polyol Producers (EPA) and the Commission concerning the use of sorbitol and mannitol in feed

An exchange of letters between the European Association of Polyol Producers (EPA) and the Commission concerning the use of sorbitol and mannitol in feed was sent to the Committee members.

M.02 The state-of-play of the "Ethoxyquin" dossier

In reply to the question of a delegation concerning the state-of-play of the "Ethoxyquin" dossier, a representative of the Commission indicated that due to the delays for the submission of the supplementary data by the applicant, a decision should be taken on the follow-up of the suspension measure. A proposal on such follow-up will be communicated at the next Committee meeting.

M.03 Communication from the Commission on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services" of 23.3.2020 (C(2020) 1897 final)

With respect to the ongoing Covid-19 pandemic, a Commission representative informed the Committee about the "Communication from the Commission on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services."