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Standing Committee on Plants, Animals, Food and Feed Section Animal Nutrition 09 - 11 September 2019

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SUMMARY REPORT

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

 Documents were distributed.
- A.02 Feed Additives Applications under Regulation (EC) No 1831/2003 Art. 9
 - A.02.1. AviPlus® as a feed additive for turkeys for fattening, turkeys reared for breeding and suckling piglets Annex

No discussion took place.

A.02.2. Bergazym® P100 (endo-1,4-bxylanase) as a feed additive for other birds for fattening, ornamental birds and other growing Suidae - Annex

No discussion took place.

A.02.3. Biomin® DC-C as a zootechnical feed additive for weaned piglets - Annex

A draft Regulation will be proposed at a future meeting.

A.02.4. Bactocell® (Pediococcus acidilactici CNCM I-4622) as a feed additive for all fish and shrimps and its extension of use for all crustaceans (renewal) - Annex

A draft Regulation will be proposed at a future meeting.

A.02.5. Bactocell® (Pediococcus acidilactici CNCM I-4622) as a feed additive for weaned piglets, pigs for fattening, minor porcine species (weaned and for fattening), chickens for fattening, laying hens and minor avian species for fattening and for laying and its extension of use to all growing pigs and all avian species (renewal)

A draft Regulation will be proposed at a future meeting.

A.02.6. Bacillus subtilis DSM 28343 as a zootechnical additive (gut flora stabiliser) for calves for rearing - Annex

No discussion took place.

A.02.7. Bacillus subtilis DSM 28343 as a zootechnical additive (gut flora stabiliser) for pigs for fattening - Annex

No discussion took place.

A.02.8. VevoVitall (benzoic acid) as feed additive for pigs for fattening - Annex

No discussion took place.

A.02.9. RONOZYME® WX CT/L (endo-1,4-bxylanase) as a feed additive for sows for reproduction - Annex

No discussion took place.

A.02.10. Natuphos® E (6-phytase) as a feed additive for laying hens, minor poultry and other avian species for laying - Annex

No discussion took place.

A.02.11. assessment of the application for renewal of authorisation of Biosprint® (Saccharomyces cerevisiae MUCL 39885) for sows - Annex

No discussion took place.

A.02.12. Levucell SC \circledR (Saccharomyces cerevisiae CNCM I-1077) as a feed additive for calves and minor ruminant species and camelids at the same developmental stage - Annex

No discussion took place.

A.02.13. modification of the conditions of the authorisation of BioPlus® 2B (Bacillus licheniformis DSM 5749 and Bacillus subtilis DSM 5750) for turkeys for fattening

No discussion took place.

A.02.14. FRA® Octazyme C Dry (endo-1,4-bxylanase, mannan-endo-1,4-b-mannosidase, a-amylase, endo-1,3(4)-b-glucanase, pectinase, endo-1,4-b-glucanase, protease, a-galactosidase) as a feed additive for weaned piglets and chickens for fattening

After the discussion, supplementary information on safety and efficacy will be requested to the applicant.

A.02.15. Modification of the terms of authorisation regarding the maximum inclusion level of Maxiban® G160 (narasin and nicarbazin) for chickens for fattening

The Member States have been informed that the application has been withdrawn by the applicant.

A.02.16. 3-phytase FLF1000 as a feed additive for pigs for fattening and minor porcine species for growing

After the discussion, supplementary information on efficacy will be requested to the applicant.

A.02.17. Use of preservatives in feed – Annexes

A discussion has been held. A new version of the Annex will be submitted at a future meeting.

A.02.18. conjugated linoleic acid 1362 (t10,c12)-methylester for pigs for fattening - Annex entry

No discussion took place.

A.02.19. cis-norbixin di-potassium salt (annatto F) for cats and dogs - Annex entry

No discussion took place.

A.02.20. essential oil from Elettaria cardamomum (L.) Maton when used as a sensory additive in feed for all animal species- Annex entry

No discussion took place.

A.02.21. Lutein and lutein/zeaxanthin extracts from Tagetes erecta for poultry for fattening and laying (except turkeys) - Annex entry

No discussion took place.

A.02.22. natural essential oil from Origanum vulgare L. ssp. hirtum var. Vulkan (DOS 00001) for all animal species

The Commission's representative presented the last opinion from EFSA on this product and informed on the presentation of an annex entry for the next Standing Committee.

In relation with botanical flavourings, discussion took place on the possibility to use the FEMA number for the identification of the additive with the prefix of the functional group 2(b) when the CoE number does not exist. There were no objections to this proposal.

A.02.23. Sodium selenate for ruminants (EFSA-Q-2017-00644, FAD-2017-0045) - Annex entry

The EFSA opinion was presented to the Committee. An Annex entry will be prepared for a future meeting.

A.02.24. Iron chelates of lysine and glutamic acid for all animal species (EFSA-Q-2018-00255 FAD-2018-0010) - Annex entry

The EFSA opinion was presented to the Committee. An Annex entry will be prepared for a future meeting.

A.02.25. Zinc chelates of lysine and glutamic acid for all animal species (EFSA-Q-2017-00072) - Annex entry

The EFSA opinion was presented to the Committee. An Annex entry will be prepared for a future meeting.

A.02.26. Copper chelates of lysine and glutamic acid for all animal species (EFSA-Q-2018-00011, FAD-2017-0071) - Annex entry

The draft Annex entry was discussed. The Commission will contact the applicant with respect to the verification of the chelation.

A.02.27. L-histidine monohydrochloride monohydrate for all animal species (EFSA-Q-2018-00438, FAD-2018-0013 and EFSA-Q-2018-00547, FAD-2018-0040, EFSA-Q-2018-00782) - Annex entry

The EFSA opinion was presented to the Committee. An Annex entry will be prepared for a future meeting.

A.02.28. L-arginine for all animal species (EFSA-Q-2016-00783, FAD-2016-0071; EFSA-Q-2018-00612, FAD-2018-0045) - Annex entry

The draft Annex entry was discussed. In the light of the discussions, a draft Regulation will be proposed at a future meeting.

A.02.29. L-leucine produced by fermentation with Escherichia coli NITE BP-02351 for all animal species (EFSA-Q-2018-00548, FAD-2018-0041) - Annex entry

The draft Annex entry was discussed. In the light of the discussions, a draft Regulation will be proposed at a future meeting.

A.02.30. Preparation of algae interspaced bentonite as a feed additive for all animal species

A discussion was held. The EFSA opinion is inconclusive, and the information provided by the applicant has not resolved all the issues regarding the efficacy of the product. The applicant will be contacted in order to decide on the way forward.

A.02.31. Saccharomyces cerevisiae NBRC 0203, Lactobacillus plantarum NBRC 3070 and Lactobacillus casei NBRC as a feed additive for all animal species

A discussion was held. MS required more time in order to evaluate the new information provided by the applicant.

A.02.32. Aluminosilicate of sodium, potassium, calcium and magnesium as a feed additive for pigs – information

A discussion was held. The Commission's representative informed MS that supplementary information has been requested to the applicant.

The new information provided regarding RASFF notification 2019.1459 was also discussed.

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

A presentation of the last development following the modification of General Food Law was discussed. In addition, an in-depth examination of the text has been carried out. In particular Annex I, Annex II identification and analytical methods. The JRC informed on an updating of its guideline on the analytical method for the detection of rDNA. The section on user safety has been examined. In addition, under the alignment of the Lisbon Treaty, Member States have been informed that the revision of the chapter 8 "Additives already authorised for food use" will be modified by Delegated Act, so a separate document will be provided at a further meeting. A revised document will be submitted at a future meeting.

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

A.04.1. Revision of Regulation (EC) No 68/2013 on the Catalogue of feed materials

The Commission's representative informed the Committee that the Feed Chain Task Force is finalising its suggestions to revise the Catalogue with the intention to present the draft at the next Committee.

A.04.2. Draft Modus Operandi for the maintenance of the Feed Material Register as proposed by the EU FCTF

The Commission's representative informed the Committee that the Feed Chain Task Force is finalising its draft Modus Operandi for the maintenance of the Feed Material Register including a new web site. The Task force will forward the draft to be discussed in one of the next Committees.

A.04.3. Discussion of arbitrary entries in the Feed Material Register: biomass from Ashbya gossypii, Magnesium-aspartate-hydrochloride

The Committee had a discussion on the legal status of "biomass from *Ashbya gossypii*". The Commission's representatives raised concerns that the regime of feed additives might be undermined if this biomass naturally rich in Vitamin B2 is considered a feed material and the product should be considered as a feed additive. Several Member States stated that all criteria to consider the biomass a feed material would be fulfilled. The Committee could not conclude on the issue and will come back on it in one of the next meetings.

The Committee assessed again the status of Magnesium-aspartate-hydrochloride, based on supplementary information from the feed business operator placing it on the market. The Committee concluded that it is considered a feed material, which is not covered by an entry in the Catalogue of feed materials. Thus, a listing in the Register of feed materials is necessary to accept its placing on the EU market.

A.04.4. Legal status of the use of CMIT/MIT in feeding Artemia nauplii

The Committee could not conclude on the issue and will come back on it in one of the next meetings.

A.05 List of products considered out of the scope of Regulation (EC) No 1831/2003 and list of feed additives to be withdrawn from the market.

The Commission's representative presented a new version of the working documents which had been circulated to the Committee's members, taking into account in particular a delegation's contribution received last June. A discussion took place. Some further verification of the characteristics of certain products will be carried out before establishing a draft of the envisaged measure.

A.06 Notion of "placing on the market" in relation to the intra-EU circulation of non-authorised feed additives intended for export to third-countries.

The Commission's representative reminded the "historical" background concerning the issue of the intra-EU circulation of non-authorised feed additives intended for export to third countries, including the previous discussions held within the section "Animal Nutrition" of the Standing Committee on this subject.

Further to the legal clarification of the notion of "placing on the market" provided by the Commission in the context of the legislation on GM food and feed¹, the Committee was informed that the same interpretation has to be considered for the purpose of the application of the legislation on feed additives. Both legislations refer to the same legal definition of the concept of "placing on the market", as laid down in

¹ As published in the summary report of the meeting of 3 December 2018 of the Standing Committee on Plants, Animals, Food and Feed, Section "Genetically Modified Food and Feed and Environmental Risk".

the General Food Law² and do not provide for an exclusion from their scope of products intended for export to third countries.

Accordingly, any activity involving a transfer of ownership of a feed additive within the EU constitutes a placing on the market within the meaning of Regulation (EC) No 1831/2003 and is therefore subject to a prior authorisation requirement in accordance with Article 3(1) of that Regulation, including where the product is intended to be exported to third countries at a later stage. The notion of transfer does not refer to the physical movement of goods, but to the transfer of ownership of goods to another person within the Union.

As stated on the occasion of previous meetings of the Animal Nutrition section of the Standing Committee, the production of a feed additive intended for *direct* export to third countries, *i.e.* without placing on the market in the EU, does not fall within the scope of Regulation (EC) No 1831/2003. However, feed business operators must ensure that such operation complies with relevant applicable legal requirements deriving from EU legislation such as the General Food Law, in particular Articles 12 and 17 thereof, or the Feed Hygiene Regulation.

A discussion took place. In particular, reference was made to the provisions of the Union Customs Code as regards the placing of goods under specific categories of special procedures such as transit or inward processing.

A.07 Creation of an Expert Group on Animal Nutrition.

Further to the information given on the occasion of the last meeting of the Committee, the Commission's representative indicated that the internal procedure for the creation of the Expert Group on Animal Nutrition was still ongoing.

In relation to the competence of the future Expert Group for the preparation of delegated acts, information was provided to the Committee on Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019³, which, for the animal nutrition sector, adapts Directive 2002/32/EC, Regulation (EC) No 1831/2003 and Regulation (EC) No 183/2005 to the Lisbon Treaty as far as the need to adopt delegated acts is concerned.

Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 ("medicated feed") already provides for the adoption of delegated acts as regards certain measures.

Reference was also made to the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁴ and the annex thereof concerning delegated acts. A discussion took place.

² Article 3(8) of Regulation (EC) No 178/2002 of the European Parliament and of the Council.

³ Published in the Official Journal of the EU L 198 of 25.7.2019, p. 241.

⁴ Published in the Official Journal of the EU L 123 of 12.5.2016, p. 1.

A.08 Evaluation of Regulation (EC) No 1831/2003 on additives for use in animal nutrition – update.

The Commission's representative asked the delegations to complete the survey prepared for the evaluation of Regulation (EC) No 1831/2003. The representative also thanked them for their time and effort to contribute to this exercise.

A.09 Guide to good practice for the processing of former foodstuffs for use as feed for food-producing animals – EFFPA.

The Commission's representative informed the Member States about the current state of play of the EFFPA's guide. A new version of the document has been transmitted to the Member States for their comments.

A.10 RASFF.

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 June 2019.

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

- aflatoxins in groundnuts (for wildlife feed/birdfeed) from US (3), groundnuts from Argentina (3), Bolivia (2), Sudan (3) and India;
- lead in manganese oxide from India (2) and magnesium oxide from China;
- cadmium in dog feed from Austria (2, raw materials in one case from Romania);
- ragweed seeds (Ambrosia spp) in bird feed from Austria;
- salinomycin in feed for laying quails from Lithuania;
- aliphatic hydrocarbons in pork fat from Germany;
- DDT in Japanese millet from India;
- T-2 and HT-2 toxin in wheat flour from Belgium.

Furthermore the attention was drawn to the RASFF notifications related to the presence of too high levels of several pesticide residues (chlorpyrifos, cypermethrin, thiomethoxam and fipronil) in groundnuts from India and of deltamethrin in sunflower seeds from France.

The delegation of France raised the issue of analysis of lead in products like magnesium oxide and that it is important to clarify which method of analysis (including sample preparation) has to be applied to determine the lead content.

A.11 Undesirable substances.

A.11.1. Exchange of views on issues related to undesirable substances in feed:

- Dioxins and PCBs in calcium salts of fatty acids from fish oil
- Review of maximum levels for dioxins and PCBs
- Deoxynivalenol and modified forms
- T-2 and HT-2 toxins
- Update on provisions related to unavoidable carry-over of authorised feed additives into non-target feed
- Nickel in feed
- p-phenetidine, cadmium in binders and anti-caking agents lead in game meat used in pet food
- Other issues.

Due to a lack of time the different issues have only been shortly presented but were not discussed in detail. Therefore, the proposal from the Commission's representative to organise a dedicated meeting of the working group "Undesirable substances in feed" on 30 September 2019 to discuss these issues in more detail was welcomed. It was requested to address under other issues also the point of the efficiency of crushing and oil extraction of oilseeds to make seeds of ragweed present as contaminant would no longer be able to germinate. Given that discussion is ongoing as regards the presence of tropane alkaloids in cereals and cereal products for human consumption, it might be appropriate to consider this also in more detail for cereals and cereal products intended for feed.

A.12 Review of Regulation (EU) No 152/2009.

The Commission's representative informed the Committee that a meeting of the working group "Methods of analysis" is taking place on 20 September 2019 to continue the discussions on the review of Regulation (EU) 152/2009.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of phenylmethanethiol, benzyl methyl sulphide, 2-pentylthiophene, tridec-2-enal, 12-methyltridecanal, 2,5-dimethylphenol, hexa-2(trans),4(trans)-dienal and 2-ethyl-4-hydroxy-5-methyl-3(2H)-furanone as feed additives for cats and dogs.

The draft Regulation refers to the authorisation of some flavourings for cats and dogs.

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 L-lysine base, liquid, L-lysine monohydrochloride, liquid, L-lysine monohydrochloride, technically pure, and L-lysine sulphate as feed additives for all animal species.

The draft Regulation concerns the authorisation of four forms of lysine as nutritional feed additives (amino acids).

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising a preparation of sodium molybdate dihydrate as feed additive for sheep.

The draft Regulation concerns the authorisation of sodium molybdate dehydrate as a source of the trace element molybdenum for sheep.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC.

The draft Regulation concerns the revision of the provisions in the general part and in the list of intended uses for particular nutritional purposes. Furthermore, the current Directive is replaced by a Regulation.

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 cassia gum as a feed additive for cats and dogs.

The draft Regulation refers to the re-authorisation of cassia gum as a technological additive. A discussion took place.

Vote taken: Favourable opinion.

B.06 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 weaned piglets and pigs for fattening.

The vote was not taken as the applicant has decided to withdraw the application.

M.01 New legislation on transparency and sustainability of the EU risk assessment model in the food chain.

The Commission's representative informed the Committee on the adoption of Regulation (EU) 2019/1381 of the European Parliament and of the Council⁵, which will enter into application on 27/3/2021. The attention was drawn on the main modifications brought to the General Food Law and in particular on the impact on Regulation (EC) No 1831/2003 on additives for use in animal nutrition, as far as the transparency and confidentiality issues are concerned. Collaboration between EFSA and the Commission is ongoing in order to prepare the future application of the new Regulation.

M.02 Placing on the EU market of complementary feed containing nutritional feed additives (compounds of trace elements) which are not authorised for use in water for drinking

On request of one Member State, the placing on the EU market of complementary feed containing nutritional feed additives (compounds of trace elements) which are not authorised for use in water for drinking, has been discussed. The Commission's representative clarified the fact that the use of the trace elements in water for drinking is not authorised, does not prohibit their incorporation in compound feed which is administered via water. Thus, trace elements can be incorporated into (liquid) complementary feed. However, such complementary feed shall not be used in water for drinking. Consequently, the instructions for proper use of such complementary feed shall not indicate the dosage of the complementary feed into water for drinking.

⁵ Published in the Official Journal of the EU L 231 of 6.9.2019, p. 1.