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Standing Committee on Plants, Animals, Food and Feed

Section *Animal Nutrition*

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SUMMARY REPORT

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

A.01.1. New applications (copies)

Documents were distributed.

A.01.2. Update on status of old applications under EFSA evaluation

A discussion took place based on a new version of a working document, which had been circulated to the Member States.

A short update of the old applications has been discussed. For some of them, where no requested data have been provided by the applicant, the Commission Service requested EFSA to go ahead with the assessment using the available provided information.

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.

A new Annex will be proposed at a future meeting.

A.02.2. Levucell SC® (Saccharomyces cerevisiae CNCM I-1077) as a feed additive for calves and minor ruminant species and camelids at the same developmental stage – Annex.

A new Annex will be proposed at a future meeting.

A.02.3. Efficacy of EB15 10 (Bacillus subtilis DSM 25841) as a feed additive for weaned piglets and weaned minor porcine species – Annex.

A new Annex will be proposed at a future meeting.

A.02.4. Safety and efficacy of 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 Annex will be proposed at a future meeting.

A.02.5. Safety and efficacy of 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 new Annex will be proposed at a future meeting.

A.02.6. Efficacy of ZM16 10 (Bacillus amyloliquefaciens DSM 25840) as a feed additive for weaned piglets and minor porcine specie – Annex.

A new Annex will be proposed at a future meeting.

A.02.7. Assessment of the application for renewal of authorisation of ECONASE® XT (endo-1,4-b-xylanase) as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding – Annex.

A discussion has been hold on some open issue provided by EFSA opinion. The discussion will continue at the next meeting.

A.02.8. Safety for the environment of Monimax® (monensin sodium and nicarbazin) for chickens for fattening, chickens reared for laying and for turkeys for fattening – Annex.

A new Annex will be proposed at a future meeting.

A.02.9. Safety and efficacy of 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 Annex will be proposed at a future meeting.

A.02.10. Assessment of the application for renewal of authorisation of Biosprint® (Saccharomyces cerevisiae MUCL 39885) for dairy cows and horses – Annex.

A draft Regulation will be proposed at a future meeting.

A.02.11. Efficacy of RONOZYME® WX (endo-1,4-b-xylanase) as a feed additive for laying hens – Annex.

A draft Regulation will be proposed at a future meeting.

A.02.12. Safety and efficacy of APSA PHYTAFEED® 20,000 GR/L (6-phytase) as a feed additive for turkeys for fattening, turkeys reared for breeding and minor poultry species – Annex.

A new Annex will be proposed at a future meeting.

A.02.13. Safety and efficacy of APSA PHYTAFEED® 20,000 GR/L (6-phytase) as a feed additive for piglets (suckling and weaned) and growing minor porcine species – Annex.

A new Annex will be proposed at a future meeting.

A.02.14. L-lysine monohydrochloride and concentrated liquid L-lysine (base) produced by fermentation using Corynebacterium glutamicum strains NRRL-B-67439 or NRRL B-67535 for all animal species (EFSA-Q-2018-00266, FAD-2018-0012 and EFSA-Q-2018-00507, FAD-2018-0037) – Annex entry

The Annex was discussed. A draft Regulation will be prepared for vote in one of the next Committees.

A.02.15. L-threonine produced by fermentation with Escherichia coli CGMCC 11473 as a feed additive for all animal species (EFSA-Q-2018-00695, FAD-2018-0051) – Annex entry

The Annex was discussed. A draft Regulation will be prepared for vote in one of the next Committees.

A.02.16. Butylated Hydroxy Anisole for all animal species

A discussion was held. EFSA opinion is inconclusive, as the information provided by the applicant after the EFSA Opinion in 2018 has not resolved the issue regarding the safety of the product in cats. An Annex entry will be prepared to be discussed during a next Committee meeting.

A.02.17. *Lactococcus lactis* NCIMB 30160 as a feed additive for all animal species

A discussion was held. A new Annex entry will be prepared to be discussed during a next Committee meeting.

A.03 Feed marketing Regulation (EC) N° 767/2009

A.03.1. Revision of Regulation 68/2013 on the Catalogue of feed materials

An in-depth evaluation of the draft update of the Catalogue of feed materials received from the FCTF took place. The next Committee will continue the discussions with the remaining chapters of Part C of the Catalogue.

A.03.2. Modus Operandi for the maintenance of the Feed Material Register elaborated by the EU FCTF

The Modus Operandi received from the FCTF was presented. The comments from the Member States will be forwarded to the FCTF. The Commission's representative will forward the access code to the Feed Material Register to the Member States in order to allow the competent authorities access to not publicly available information on the entries.

A.03.3. Discussion of borderline products: biomass from A*shbya gossypii*, Palmitoylethanolamide (PEA); Disodium ethylenediaminetetraacetate (EDTA); carbon with a nano-size pore structure

A profound discussion of the legal status of the biomass from A*shbya gossypii* delivered arguments for the classification as feed additive and as feed material. No conclusion could be drawn, but the Commission's representatives reiterated their position that the industry should be encouraged to prepare an application based on Regulation (EC) 1831/2003 for Vitamin B2 produced by a non-GMM. The Committee will come back on the issue.

The Committee concluded that Palmitoylethanolamide (PEA) could be classified as a feed material. The feed business operators placing PEA on the market should be in particular warned to comply with Article 13 of Regulation (EC) N° 767/2009.

Disodium ethylenediaminetetraacetate (EDTA): postponed to the next meeting.

Based on a product description received from a company, the Committee discussed the legal status of “carbon with a nano-size pore structure”. It concluded that the product falls within the scope of Regulation (EC) 1831/2003. Subsequently to a potential authorisation as a feed additive, an application for a dietetic feed containing the product could be envisaged.

A.03.4. Placing of the *Asparagopsis taxiformis* meal as feed material on the market

The Committee discussed the supplementary information prepared from the company. Concerns about the reduced feed uptake and the iodine and bromine content remain. The Committee will come back on the issue.

A.03.5. Legal status of the use of CMIT/MIT in feeding *Artemia nauplii*

The Committee continued its discussion of the legal status of the two applications of CMIT/MIT in feeding *Artemia nauplii*. Two Member States explained that they would consider CMIT/MIT to be a feed additive, whereas others supported the Commission services who indicated that the criteria for a processing aid would be fulfilled. The Committee will come back on the issue.

A.04 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 an updated version of the working documents which have been circulated to the Committee's members. In particular, transitional measures related to additives to be withdrawn from the market and to products subject to a modification of status with regard to the scope of Regulation (EC) No 1831/2003, were proposed.

An exchange of views took place.

It was clarified that the scope of the draft measure will be limited to the list of products which has been so far the subject of the discussions within the Committee, as referred to in the two working documents.

A.05 Guides to good practice

The Commission’s representative informed the Member States about the current state of play of the different guides of practice that are underway.

A.06 Discussion on amending Regulation (EC) No 429/2008.

The discussion on Annex II Section III has started. The new approach on evaluation on safety for target species has been presented. Some of the Member States raised their concerns on the extrapolation system from major to minor species. EFSA colleagues, present to the discussion, clarified several points on this aspect. The Commission's service pointed out the necessity to harmonise and simplify the definitions of the animal species and animal categories to avoid an overlap in the authorisation system. Several Member States agreed on the reduction of the details of new proposal. Denmark, supported by several Member States, requested to re-open the discussion on the new proposal on analytical method for the detection of rDNA considering it disproportionate and as a possible cause of concerns for many products.The revision of Regulation (EC) No 429/2008 in accordance with the new Transparency Regulation (Regulation (EU) 2019/1381) was also introduced to the Member States. The modifications will concern, in particular:

- The requisites and procedure for the assessment of confidentiality;
- The introduction of standard data format;
- The notification of commissioned studies;
- The possibility to request pre-submission advice (for new applications) and advice on notified studies (for renewals);

- Public consultation on studies presented (for applications) and planned (for renewals).

An indicative timeline was also presented. The first discussion is expected to take place in the PAFF Committee of April and a vote presumably in September 2020.

A revised document will be submitted at a future meeting.

A.07 RASFF

A.07.1 Update and exchange of views on 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 November 2019.

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

- aflatoxins in groundnuts from Argentina and Sudan;

- ragweed seeds (*Ambrosia* spp) in sunflower seeds from Romania and from Bulgaria, in oats from Croatia and in seed mixture from Hungary;

- ethoxyquin as pesticide residue in feed material (red fruits) for birds;

- lasalocid sodium in complete feed for turkeys from Poland.

Furthermore the attention was drawn to the RASFF notification on the presence of the unauthorised feed additive olaquindox in feed for ducks from Bulgaria. The Bulgarian delegation confirmed that investigations have been carried out and that it is confirmed to be an isolated incident.

A.08 Undesirable substances

A.08.1 Exchange of views on issues related to undesirable substances in feed (follow-up on discussions at the WG meeting of 30 September 2019).

Maximum levels for dioxins and PCBs in calcium salts of fatty acids from fish oil

Additional data on the presence of dioxins, dioxin+ dioxin-like PCBs and non-dioxin-like PCBs in the fish oil used for the production of calcium salts of fatty acids and the levels found in the resulting calcium salts of fatty acids have been provided by the Spanish authority.

The data provided indicate that there should be no problem for purchasing fish oil batches in order to produce compliant calcium salts from fish oil.

Therefore, on the basis of the available data, it is proposed not to change the current maximum levels for dioxins (1.25 ng WHO-PCDD/F-TEQ/kg), the sum of dioxins and dioxin-like PCBs (4.0 ng WHO-PCDD/F-PCB-TEQ) and for non-dioxin like PCBs (30 µg/kg) applicable to calcium salts of fatty acids from fish oil.

Review of the maximum levels for dioxins and PCBs following EFSA opinion

Issues discussed at WG on 30 September

- Analytical aspects – feasibility of achieving lower levels. The presented results reflect limitations of currently applied methods to achieve lower limits of quantification, although this is possibly related to the fact that currently applied methods are optimised for the control of current MLs. The EURL for halogenated POPs in feed and food has

been asked to explore the possibilities to achieve lower levels of quantification without increasing the cost of analysis, without increasing the time needed for analysis and maintaining the possibility to use screening methods for checking compliance.

- Furthermore, data were provided highlighting that the EFSA database does not (always) reflect background level of certain feed materials and lowering maximum levels on the basis of the data available to EFSA could create a potential issue for e.g.

- Vegetable oils and derived products
- Binders and anticaking agents (clays)
- Trace elements
- Premixtures

In this context, the difficulties and the high burden to submit data to EFSA was again highlighted.

- Reduction of the overall dioxins/PCB load of feed by focusing controls on certain feed materials (in particular at risk such as artificially dried feed materials).

Deoxynivalenol and modified forms

It is necessary to amend the current guidance levels for compound feeds in Commission Recommendation (EC) 2006/576 based on the NOAELs (No Observed Adverse Effect Levels) of the sum of deoxynivalenol (DON), 3-acetyl-DON, 15-acetyl-DON and DON-3-glucoside into the different animal species as determined in the EFSA opinion.

Furthermore, it needs to be decided if the guidance levels will apply for enforcement reasons to the parent compound DON only (but providing sufficient protection to Don and its modified forms) or to the sum of DON and its modified forms.

In addition, it is appropriate to extend the guidance levels to other feed materials such as beet pulp, etc.

It was also mentioned that also for zearalenone, guidance levels should be established for additional feed materials such as beet pulp and soya hulls (cf. RASFF notifications).

T-2 and HT-2 toxin

It is proposed to establish guidance levels for the sum of T-2 and HT-2 toxin. These guidance levels should for compound feed be established based on the NOAELS and LOAELs (Lowest Observed Adverse Effect Levels) determined by EFSA and for feed materials based on available occurrence data.

Update on provisions related to unavoidable carry-over of authorised feed additives into non-target feed.

The update relates to changes in conditions of authorisation for diclazuril and salinomycin-sodium requiring a change in provisions, to include the information currently in recitals of Directive (EC) 2009/8 as endnotes/footnotes, to apply the same definition for non-target feed as provided for in Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC and to the provisions for "other animal species" are applicable for "other animal species and other categories within an animal species".

No comments were made as regards the proposed changes.

Nickel in feed

Based on the available data it might be appropriate to establish maximum levels for nickel in certain feed additives and feed materials.

P-phenetidine, cadmium in binders and anticaking agents, cadmium in copper, lead in game meat used in pet food

Based on the information provided, it might be appropriate to amend the current maximum levels for cadmium in copper and for lead in game meat used in pet food. The Committee was updated on the analytical aspects related to the analysis of p-phenetidine in fish meal and compound feed. The issue of analysis of cadmium in binders and anticaking agents was raised.

Ergot alkaloids in feed

Based on the EFSA opinion on ergot alkaloids in feed and food (2012) and the EFSA report on human and animal exposure to ergot alkaloids (2017) and the orientation values as discussed in Germany for the protection of animal health , it seems appropriate to consider the setting of guidance values at EU level for ergot alkaloids in feed to ensure animal health protection.

Pyrrolizidine alkaloids and tropane alkaloids in feed

Information was provided on the ongoing discussions on the setting of maximum levels for pyrrolizidine alkaloids and tropane alkaloids in food, with possible future consequences as regards regulatory provisions in feed.

Upon request, the Commission's representative confirmed that it is foreseen to have the Recommendation on the monitoring of inorganic arsenic in feed adopted by the Commission early 2020. Furthermore information was requested on the status of the request to EFSA on the effectiveness of crushing and oil extraction process to ensure that ragweed seeds can no longer germinate and on the risks related to the presence of hydroxymethylfurfural (HMF) in feed for bees. The Commission's representative acknowledged that there has been an unfortunate delay in sending the mandates to EFSA.

A.09 Review of Regulation (EU) 152/2009

A.09.1 Outcome of the discussions at the meetings of the WG "Methods of Analysis" on 20 September and 11 November 2019

An overview of the main changes envisaged and point under discussion was provided:

- Specific procedure in case of examination by visual inspection or by microscopy;
- Clarification as regards the use of measurement uncertainty and recovery rate and the reporting thereof;
- Provisions for moisture content in milk products, oilseeds, oleaginous fruit, minerals, mineral additives, trace elements and matrices containing a high level of volatile nitrogen to be discussed;
- Discussion on the repeatability criteria for the method for determination of the nitrogen content;
- Limit the scope of the method for the determination of the level of urea used as feed additive in ruminant feed. Work is ongoing as regards the determination of urea in feed other than ruminant feed as contaminant;

- Method for the determination of volatile nitrogenous bases to be deleted (no legal requirements for volatile nitrogenous bases);
- Determination of amino acids (except tryptophan) and of tryptophan: inclusion of reference to relevant EN standards;
- Determination of crude oils and fats: discussion on purpose and scope. Discussion on the inclusion of reproducibility criteria;
- Determination of crude fibre: discussion on reference to the fibrebag technology as screening method and on the inclusion of reproducibility criteria;
- Determination of sugar: limit the obligation to apply the method for use in energy calculation of feed;
- Determination of starch: add soya products as feed materials whereby incorrect results could be yielded by the method;
- Method for the determination of carbonates to be deleted (no legal requirements for carbonates);
- Determination of total phosphorus: inclusion of reference to relevant EN standards;
- Determination of vitamin A, of vitamin E, of the trace elements iron, copper, manganese and zinc, of halofuginone, of robenidine, of lasalocid sodium: inclusion of reference to relevant EN standards;
- Determination of diclazuril: method to be replaced by method developed by the JRC (EUR 27954) and inclusion to relevant EN standard;
- Inclusion of reference to EN standards for the determination of narasin, nicarbazin, decoquinate, monensin, salinomycin, semduramycin and maduramycin ammonium;
- Discussion on possible inclusion of reference to EN standards for authorised additives other than coccidiostats, for which currently no provisions are included in the Annex to Regulation (EC) 152/2009;
- Determination of free and total gossypol to be deleted as method is obsolete;
- Discussion on possible inclusion of reference to EN standards for undesirable substances (inorganic contaminants and nitrogenous compounds, mycotoxins and plant toxins) in feed;
- Inclusion of the reference to EN standard on the method of calculating the energy value in feed materials and compound feed for cats and dogs;
- Discussion on the elaboration of a method at EU level of calculating the energy value in feed for pigs and ruminants;
- Deletion of Annex VIII – Methods of analysis to control illegal presence of no longer authorised additives in feed, as currently more sensitive methods of analysis are used to detect the illegal presence of no longer authorised additives in feed.

It was clarified that it is the intention to propose a first amendment to Regulation (EU) 152/2009 containing issues on which an agreement can be reached within relative short notice.

However, some issues have been identified for which more discussion/work is needed before an agreement can be reached. The discussion and work on these issues will be continued in view of another future amendment to 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 erythrosine as a feed additive for dogs, cats and ornamental fish

The draft Regulation refers to the authorisation of erythrosine as a technological additive. A discussion took place.

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-threonine as a feed additive for all animal species

The draft Regulation concerns the authorisation of L-threonine as nutritional feed additive (amino acid).

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of L-tryptophan as a feed additive for all animal species

The draft Regulation concerns the authorisation of L-tryptophan as nutritional feed additive (amino acid).

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation correcting the Swedish language version of Regulation (EU) No 68/2013 on the Catalogue of feed materials

The draft Regulation concerns the correction of the Swedish version of the Catalogue of feed materials.

Vote taken: Favourable opinion.

M.01 Information about a product listed in the Register of feed materials containing at least 40% of betaine

One Member State informed about a product listed in the Register of feed materials containing at least 40% of betaine. With respect to the production process of this product, it appears that the product undergoes, based on the feed material "beet molasses, betaine rich" additional extraction steps with the aim of purifying betaine and increasing its content. Therefore, the Committee concluded that this product would fall within the scope of Regulation (EC) 1831/2003. Moreover, the Member State notified the placing on the market of a product with a standardized betaine content (30%, 33%, 35%, 40% or 50%). Depending on the desired betaine content, the feed additive "betaine anhydrous" (3a920) is added to betaine-rich feed materials. A Commission's representative clarified that the feed business operator responsible for the labelling of the feed material shall in particular ensure compliance with Article 16(2) of Regulation (EC) N° 767/2009.

M.02 Ethoxyquin

In reply to a delegation's question, the Commission's representative and a representative of EFSA updated the Committee on the state-of-play concerning the status of ethoxyquin as a feed additive. In particular, some supplementary data are still

expected to be submitted shortly by the applicant, which would allow the finalisation of the EFSA's evaluation hopefully before the summer of 2020. In parallel, work is ongoing as regards analytical aspects related to the impurity *p*-phenetidine in the context of Directive 2002/32/EC on undesirable substances in animal feed.