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Health and Food Safety Directorate General

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 24 APRIL 2018 - 25 APRIL 2018

(Section Animal Nutrition)

CIRCABC Link: https://circabc.europa.eu/w/browse/221bcfc7-95e2-4d83-b46d-0f02ba6705f1

- 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.

 ECONASE® XT (endo-1,4-b-xylanase) as a feed additive for laying hens Annex

A discussion was held. A draft Regulation will be presented in a future meeting.

 $ECONASE \hbox{\it \&} \ XT \ (endo-1,4-b-xylanase) \ as \ a \ feed \ additive \ for \ pigs \ for \ fattening-Annex \\$

A discussion was held. A draft Regulation will be presented in a future meeting.

Calsporin® (Bacillus subtilis DSM 15544) as a feed additive for pigs for fattening – Annex

A discussion was held. A draft Regulation will be presented in a future meeting.

Lactococcus lactis NCIMB 30160 as a feed additive for all animal species

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

Sacox® microGranulate (salinomycin sodium) for rabbits for fattening

A discussion was held. An Annex will be presented in a future meeting.

Coxiril® (diclazuril) for pheasants – Annex

A discussion was held. A new Annex will be presented in a future meeting.

Pediococcus pentosaceus DSM 32291 as a silage additive for all animal species - Annex

A discussion was held. A draft Regulation will be presented in a future meeting.

natural mixtures of talc (steatite) and chlorite $(E\ 560)$ as a feed additive for all animal species

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

 $\label{eq:cylactin} \textbf{Cylactin} \textbf{\& } \textbf{(Enterococcus faecium NCIMB 10415)} \textbf{ as a feed additive for pigs for fattening} - \textbf{Annex}$

A discussion was held. A draft Regulation will be presented in a future meeting.

Alterion NE \circledR (Bacillus subtilis DSM 29784) as a feed additive for minor poultry species – Annex

A discussion was held. A draft Regulation will be presented in a future meeting.

3-phytase FLF1000 as a feed additive for chickens reared for laying and minor poultry species – Annex

A discussion was held. A new Annex will be presented in a future meeting.

Sodium and potassium alginate for pets, other non food-producing animals and fish - Annex

A discussion was held. A draft Regulation will be presented in a future meeting.

Bacillus amyloliquefaciens (NCIMB 30229) as a silage additive for all animal species

After the discussion, it was requested to contact the applicant for future information.

ENZY CARBOPLUS® (endo-1,4-betaxylanase and endo-1,3(4)-beta-glucanase) as a feed additive for avian species, weaned piglets and minor weaned porcine species - Annex

A discussion was held. A draft Regulation will be presented in a future meeting. and supplementary information will be requested to the applicant to complete the evaluation on efficacy for laying hens.

Monimax (monensin sodium and nicarbazin) for turkeys for fattening - Annex

A discussion was held. A draft Regulation will be presented in a future meeting.

Bacillus subtilis DSM 28343 as a feed additive for piglets – Annex

A discussion was held. A draft Regulation will be presented in a future meeting.

butylated hydroxyanisole (BHA) as a feed additive for all animal species – Annex

After the discussion, it has been requested to ask for supplementary information to the applicant to complete the safety evaluation for cats. The re-authorisation procedure is suspended waiting for the final decision on safety for cats.

ENZY CARBOPLUS® (endo-1,4-betaxylanase and endo-1,3(4)-beta-glucanase) as a feed additive for avian species, weaned piglets and minor weaned porcine species – Annex.

As above.

Coxiril® (diclazuril) for chickens reared for laying - Annex

A discussion was held. A draft Regulation will be presented in a future meeting.

Bacillus subtilis DSM 28343 as a feed additive for calves for rearing

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

Sodium saccharin for piglets (suckling and weaned), pigs for fattening, calves for rearing and calves for fattening (EFSA-Q-2010-01228)

This point was not discussed, as the final opinion was not published.

Benzoic acid for suckling piglets, weaned piglets, pigs for fattening, sows for reproduction, sows in order to have benefit in piglets, minor porcine species, chickens for fattening, chickens reared for laying, laying hens, breeding hens, turkeys for fattening, turkeys for breeding purposes, turkeys reared for breeding, minor poultry species (EFSA-Q-2016-00858).

A draft Annex entry prepared by the Commission was discussed. The Commission's representative informed on the proposal of the applicant for the Annex entry. A draft proposal will be submitted for vote at the next Committee.

Ponceau 4R for dogs, cats and ornamental fish (EFSA-Q-2012-00331 / FAD-2010-0349).

The Commission's representative updated on the situation of the application. The applicant is working on a method of analysis for compound feed and premixtures.

Hydroxy analogue of methionine and its calcium salt for all animal species (EFSA-Q-2016-00370)

The opinion was presented and an Annex entry will be prepared for the next Committee.

Zinc-L-selenomethionine for all animal species (EFSA-Q-2016-00554)

The opinion was presented and an Annex entry will be prepared for the next Committee.

Ethyl ester of B-apo-8'-carotenoic acid (B-apo-8-ester) for poultry for fattening and poultry for laying (FAD-2010-0224)

The Commission's representative updated on the situation of the application. The applicant provided complementary information to demonstrate the safety of the additive in eggs intended for pasta and fined bakery. The information was submitted to EFSA for assessment.

Indigo carmine (FAD 2010-0346)

The Commission's representative updated on the situation of the dossier. The information submitted by the applicant to demonstrate that the additive with a purity of 85 % was safe did not clarify EFSA concerns. The applicant has been requested to provide new information to respond to EFSA concerns. The applicant is also working on the method of analysis in premixtures and compound feed.

Titanium dioxide (FAD 2010-0297)

The Commission's representative updated on the situation of the application and on the classification of this additive under the CLP Regulation (classification, labelling and packaging of chemical substances and mixtures). The applicant has to perform additional studies on reproduction.

Iron oxide (FAD 2010-0203)

The Commission's representative updated on the situation of the application. The applicant withdrew the application for horses and will provide additional information to clarify the concerns expressed in the EFSA opinion.

Erythrosine (FAD 2010-0382)

The Commission's representative updated on the situation of the application. The applicant is working on a fish tolerability study to clarify EFSA concerns.

Botanical flavourings and CDF flavourings.

The Commission's representative updated on the situation of the assessment of chemical defined flavourings and botanical flavourings on the applications submitted by the FEFANA Consortium (FFAC).

A.03 List of the products considered out of the scope of Regulation (EC) No 1831/2003.

The Member States' representatives have been invited to examine the list of the products not any more falling under the scope of Regulation (EC) No 1831/2003. A new proposal will be discussed in a future meeting.

A.04 Discussion on a the possibility to propose a correcting Commission Implementing Regulation amending Commission Implementing Regulation (EU) 2018/249 as regards the manufacturing method for certain additives - request from France.

France proposed to correct Commission Implementing Regulation (EU) 2018/249 to prevent the production of an amino acid from human hair.

The Commission's representative informed that Animal by-products legislation, Regulation EC No 1069/2009, excludes the use of human hair in hydrolysed proteins (amino acids are regarded as hydrolysed proteins). The health certificate establishes that the veterinarian in the Third country certify that only category 3 material (parts of laughter animal fit for human consumption) can be used in the production of hydrolysed protein.

Section XVI of Annex III to Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin establishes that amino acids intended for food use must derive from animals fit for human consumption. This is also reflected in the import certificate.

A.05 Method of analysis for official control of carbamide (urea).

The EURL presented the report on the analysis of carbamide (urea) in feed. The Union method of analysis based on spectrophotometry, established by Commission Regulation (EC) 152/2009 can show a lack of specificity, leading to false positive samples when analysing feed samples containing animal by-products such as pet food. Considering that ruminant feed has a significant different composition compared to pet food, it is possible that the Union method is able to deliver reliable results on the quantity of urea in ruminant feed. The method of analysis based on liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS) is suitable for the determination of urea in the pet food. Although there are no validation data available for the use of the enzymatic method for the analysis of urea in pet food, the enzymatic measurement is considered to be more specific for the determination of urea than the Union method.

Given that the enzymatic and the LC-MS/MS method possesses in principle a higher selectivity and are widespread used by official laboratories, the EURL considers it important to evaluate the applicability of the latter methods for the determination of urea also in ruminant feed.

One delegation indicated the preference the use of the enzymatic method as the use of LC-MS/MS requires expensive equipment while another delegation indicated that the

enzymatic method was still under validation and therefore some prudence is required at this stage.

A.06 Feed hygiene - Regulation (EC) No 183/2005.

Commission working document - Guidance document on the implementation of certain provisions of Regulation (EC) No 183/2005 on the hygiene of feedstuffs

The Commission's representative presented for discussion a new version of the document. After the comments from Member States, the document has been improved although there are some issues that need further discussion and agreement. Member States requested to the Commission to organize a new face-to-face meeting of the Working Group to end the discussion. The Commission's representative agrees on trying to organise that meeting.

Other issues related

No additional topics were commented.

A.07 RASFF.

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 February 2018.

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

- 1. aflatoxins in groundnuts from Sudan (5), Gambia (3), US (1), China (1) and India (1);
- 2. aflatoxins in mixed corn from Austria;
- 3. ragweed (*Ambrosia* spp) in sorghum from France and in sunflower seeds from Hungary;
- 4. lead in complementary feed (*Psyllium* husks) for horses from the US;
- 5. cadmium in fish meal from Mauritius;
- 6. maduramycin in complete feed for piglets (too high level of cross-contamination);
- 7. propamocarb in lupin from Poland (residue of plant protection product);
- 8. deoxynivalenol and zearalenone in maize corn cob used as carrier for xylooligosaccharides from China;
- 9. dioxins in rapeseed from Ukraine;
- 10. dioxins in bentonite from India used as mycotoxin binder. The levels of dioxins found in two consignments of complementary feed from Germany above the action threshold are related to the bentonite used in these consignments of complementary feed.

Following the findings of aflatoxins in groundnuts from Sudan and Gambia, the Commission's representative informed the Committee of the intention of the Commission services to impose a health certificate (i.e. requirement of sampling and analysis prior to export to the EU) for groundnuts from Bolivia, from Gambia from

Madagascar from Senegal and from Sudan, all with a control frequency at import of 50 % (transfer from Commission Regulation (EC) No 669/2009 to Commission Implementing Regulation (EU) No 884/2014).

A.08 Undesirable substances.

A.08.1 Discussion on amendment of the annexes of Directive 2002/32/EC

It was highlighted that it is proposed that the maximum level for dioxins and PCBs in binders and anti-caking agents is also applicable to these feed additives when used to control radionuclide contamination or for the reduction of the contamination of feed by mycotoxins.

One delegation was of the opinion that a higher level of arsenic in leonardite and peat could be established given the low incorporation rate of these feed materials in compound feed.

A.08.2. Further exchange of views on nitrates and nitrites in feed

An update was provided to the Committee.

A.08.3. Discussion on provisions in Directive 2002/32/EC related to the presence of Ambrosia seeds

The Commission representative indicated that further discussion is needed to determine to which extent the decontamination process fall within the scope of Regulation (EU) 2015/786, on the appropriateness of making a distinction between viable and non-viable seeds and on the footnote providing under strict conditions a derogation of the cleaning requirement for contaminated seeds intended for milling and crushing.

A delegation highlighted the importance of the distinction between viable and non-viable seeds and that this is easy to determine, to maintain the derogation provided by the footnote and indicated that according to their opinion milling, crushing and extraction processes fall outside the scope of Regulation (EU) 2015/786.

A.08.4. Presence of THC in hemp derived products

This point was postponed to a next meeting.

A.08.5. Follow-up to recent EFSA opinions/statements on undesirable substances

The Committee was informed on the organisation of the mycotoxin forum on 14-15 May 2018.

A.08.6 Undesirable substances of relevance for future monitoring in feed

A short exchange of views has taken place.

A.08.7. Other issues

The Committee was informed of the work programme of the EURL for metals and nitrogenous compounds and the EURL for mycotoxins and plant toxins.

One delegation requested more information as regards <u>Commission Recommendation</u> (EU) 2018/464 of 19 March 2018 on the monitoring of metals and iodine in seaweed, halophytes and products based on seaweed.

The Commission's representative indicated that this monitoring recommendation aims to obtain more information on the presence of arsenic, cadmium, iodine, lead and mercury in seaweed and halophytes given their increasingly important contribution to the consumption patterns of certain EU consumers. Following the request from several Member States, this Recommendation has been extended to seaweed and halophytes used for feed for the analysis of arsenic, lead, cadmium and mercury.

A.09 Review of Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed.

The Commission's representative indicated that information was already received from several delegations as regards the issues to be reviewed in Commission Regulation (EC) No 152/2009. Based on the input received until now, it is evident that the review has to take place in two phases: first phase whereby the amendments relate to suggested changes, which are straightforward and can be finalised within in a short period of time and a second phase where the amendments relate to changes which might require more lengthy discussions.

A.10 Feed marketing - Regulation (EC) N° 767/2009.

Dietetic feed (Directive 2008/38/EC) - state of play of pending evaluations, new applications and draft Regulation for repealing the Directive

A draft text to repeal Directive 2008/38 has been presented which contained the complete list of intended uses. The Commission's representative explained some amendments in the general part and highlighted that the existing intended uses with vague or meaningless descriptions of the essential nutritional characteristics which are not defended by an application for a revision will be deleted with a phase out period to allow interested parties to come with a new application.

Feed material classification

Discussion postponed due to time constrains.

Revision of the FEDIAF Code of Good Labelling Practice

The draft code was discussed and several issues were raised by the delegations. The Member States were asked to send in additional comments by 15th May 2018.

A.11 Processing aids in feed.

A discussion took place based on the working document distributed to the delegations. Member States were asked to report about the experiences with the provision established in point 4 in Part A of the Catalogue of feed materials. Moreover, the implementation of point 5 in Part A of the Catalogue of feed materials was discussed.

It was clarified that processing aids do not fall within the scope of Regulation (EC) No 1831/2003 and that, with respect to the legal definitions, a specific substance could be considered as a processing aid or as a feed additive; the difference lies between "used in a production process and residual in feed" and "added to feed".

Finally, the criteria laid down in the legal definition of processing aids (Article 2(2)(h) of Regulation (EC) No 1831/2003) have been exemplary assessed for several substances in order to determine whether these substances could be considered processing aids or not.

A.12 A.O.B.

No items raised.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid as feed additive for chickens for fattening and chickens reared for laying (holder of the authorisation Novus Europe S.A./N.V.).

The draft Regulation refers to an authorisation as zootechnical additive. A discussion took place.

Vote taken: Unanimity.

B.02 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 minor porcine species for fattening and for reproduction (holder of authorisation DSM Nutritional Products Sp. z o. o.).

The draft Regulation refers to an authorisation as zootechnical additive. A discussion took place.

Vote taken: Unanimity.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the denial of authorisation of riboflavin (80 %) produced by Bacillus subtilis KCCM-10445 as a feed additive belonging to the functional group of vitamins, pro-vitamins and chemically well-defined substances having similar effect.

The draft measure aims to deny the authorisation of riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445 as an existing product (vitamin B2), further to the EFSA's opinion of 7 March 2018. Other applications for authorisation of riboflavin (as existing product currently on the market) are being processed separately.

The Commission's representative presented the preliminary working document which has been sent to the Member States and which is still under internal consultation.

A discussion took place. In particular, a representative of the EU Reference Laboratory for feed additives provided information on the aspects related to the reference samples and method of analysis for the additive concerned.

Vote Postponed

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of Copper(II) diacetate monohydrate, Copper(II) carbonate dihydroxy monohydrate, Copper(II) chloride dihydrate, Copper(II) oxide, Copper(II) sulphate pentahydrate, Copper(II) chelate of amino acids hydrate, Copper(II) chelate of protein hydrolysates, Copper(II) chelate of glycine hydrate (solid) and Copper(II) chelate of glycine hydrate (liquid) and amending Regulations (EC) No 1334/2003 and No 479/2006.

The draft Regulation concerns the authorisation of nine compounds of copper as feed additives belonging to the functional group of trace elements.

Vote taken: Unanimity.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation correcting the Dutch language version of Regulation (EU) No 68/2013 on the Catalogue of feed materials.

The draft Regulation concerns two corrections in the Dutch Catalogue of feed materials.

Vote taken: Unanimity.

C.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of the authorisation of benzoic acid as a feed additive for weaned piglets and pigs for fattening and repealing Regulations (EC) No 1730/2006 and No 1138/2007 (holder of authorisation DSM Nutritional Products Sp. z o. o.).

The draft Regulation refers to an authorisation as zootechnical additive. It will be submitted for the vote in a future meeting.

C.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex I to Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group.

A discussion took place. The Commission will prepare a modified version after the comments from the Member States.