

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 23 MAY 2016 - 24 MAY 2016

(Section Animal Nutrition)

CIRCABC Link: https://circabc.europa.eu/w/browse/e360a1b3-c86e-4696-8122-f8c95d0412c5

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. a natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) as feed additive for all animal species – Annex

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

A.02.2. friedland clay (montmorillonite-illite mixed layer clay) when used as a technological additive for all animal species – Annex

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

A.02.3. malic acid, sodium malate and calcium malate for all animal species – Annex

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

A.02.4. propionic acid, sodium propionate, calcium propionate and ammonium propionate for all animal species – Annex

A discussion was taken. A new Annex will be presented in a future meeting. A discussion on the use in water of some of these additives was raised from some Member States.

A.02.5. formic acid, ammonium formate and calcium formate for all animal species – Annex

This item was not discussed.

A.02.6. lactic acid and calcium lactate for all animal species – Annex

This item was not discussed.

A.02.7. sodium benzoate as silage additive – Annex

This item was not discussed.

A.02.8. acetic acid, sodium diacetate and calcium acetate for all animal species – Annex

This item was not discussed.

A.02.9. sorbic acid and potassium sorbate for all animal species – Annex

This item was not discussed.

A.02.10. citric acid for all animal species - Annex

This item was not discussed.

A.02.11. concentrated liquid L-lysine (base), L-lysine monohydrochloride and L-lysine sulphate produced using different strains of Corynebacterium glutamicum for all animal species based on a dossier submitted by AMAC/EEIG

The opinion was discussed. Annex entries will be prepared for the compounds with a positive EFSA opinion. As EFSA could not conclude on the safety of several products, the Commission will contact the applicant to explore the follow-up.

A.02.12. L-lysine monohydrochloride produced by fermentation with Escherichia coli CGMCC 7.57 for all animal species based on a dossier submitted by Feedway Europe NV

The new opinion was discussed. As EFSA concluded that the manufacturing strain is safe, Escherichia coli CGMCC 7.57 will be included in the upcoming draft Regulation for the re-authorisation of L-lysine monohydrochloride.

A.02.13. L-threonine technically pure, produced by fermentation with Escherichia coli CGMCC 7.58 for all animal species based on a dossier submitted by Feedway Europe NV

The new opinion was discussed. As EFSA concluded that the manufacturing strain is safe, Escherichia coli CGMCC 7.58 will be included in the upcoming draft Regulation for the re-authorisation of L-threonine.

A.02.14. Manganese hydroxychloride as feed additive for all animal species

The opinion was briefly discussed. As all opinions for the manganese compounds to be re-authorised are now available, the Commission services will draft an Annex entries for the manganese compounds to be discussed in one of the next meetings.

A.03 Withdrawal from the market of certain feed additives for which no applications for authorisation were submitted before the deadline provided in Regulation (EC) No 1831/2003.

The list of the additives to be withdrawn from the market was presented. Subject to future verifications on specific additives, a general consensus was achieved on that document. Member States reiterated their request to have a short transitional period for additive and premixture in particular, but also for compound feed.

A.04 RASFF.

The Commission representative informed the Committee on the following RASFF notifications related to undesirable substances in animal feed, issued since the meeting of the Committee in April:

- prohibited substance metronidazole in feed materials made from whey powder from the Netherlands with raw materials from Germany;
- lead in venison meal from Poland;
- aflatoxins in shelled peanuts from Brazil.

Referring to the discussions as regards harmonised guidelines for RASFF notification which took place in the meetings of January and February of the Committee this year, the Commission representative informed the Committee that upon further examination and exchange of views, it has been decided to issue a RASFF notification related to the presence of tylosin in several batches of a feed additive (coccidiostat) (RASFF notification 2016.0662 dd. 24/05/2016). The Committee was furthermore informed of the intention of the Commission to address a mandate to EFSA for scientific assistance to RASFF notifications to propose a methodology for a risk-based classification of RASFF notifications on contaminants in feed and food, including veterinary drug residues.

The Commission representative informed also the Committee that the Commission will examine the RASFF notifications from recent years related to the presence of unacceptable levels of dioxins in dried feed materials (corn, apple pomace, rapeseed, peas) from Ukraine to verify if the congener pattern provides evidence of bad drying practices. If this is the case, then appropriate measures are to be considered.

A.05 Undesirable substances.

A.05.1. Exchange of views on a draft Recommendation on nitrites and nitrates in feed

As the document was not made available the point was not discussed. The Commission representative committed to submit to the Committee a draft Recommendation for discussion before the summer break.

A.05.2. Other issues

EFSA opinion on zearalenone and its modified forms

The Committee was informed on the recent EFSA opinion on the appropriateness to set a group health-based guidance value for zearalenone and its modified forms (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4425/pdf).

The modified forms of zearalenone (ZEN) identified are phase I and phase II metabolites. Phase I metabolites are mainly formed through reduction. Phase II metabolites are formed by conjugation of ZEN and its phase I metabolites with glucose or sulfate, and in animals glucuronic acid. The few data on the occurrence of modified forms of ZEN indicated that cereal-based foods are the main source, containing amounts varying from a few up to 100% of ZEN. Most of the phase I metabolites have oestrogenic activity and it is assumed that their combined action will be additive. The CONTAM Panel found it appropriate to set a group TDI of 0.25 ug/kg bw per day expressed as ZEN equivalents for ZEN and its modified forms (phase I and phase II metabolites). To account for differences in in vivo oestrogenic potency, each phase I metabolite was assigned a potency factor relative to ZEN to be applied to exposure estimates of the respective ZEN metabolites. It was assumed that conjugates (phase II metabolites) of ZEN and its phase I metabolites, which per se have no oestrogenic activity, will be cleaved releasing ZEN and its phase I metabolites. These conjugates were assigned the same relative potency factors as their aglycones.

The Committee was informed that given the high relative potency factor given to certain modified forms (e.g. a potency factor of 60 to α-zearalenol) the presence of certain modified forms in food of animal origin could result that food of animal origin is a more important contributor to the overall human exposure to zearalenone and its modified forms than previously assessed. So the presence of zearalenone and its modified forms in feed is not only relevant as regards the possible adverse animal health effects but also could result in levels of zearalenone and its modified forms in food of animal origin significantly contributing to the human exposure. The Committee was informed that discussions on the follow-up to the EFSA opinion are currently ongoing in the Expert Committee "Agricultural contaminants in food" and that any possible follow-up action shall be discussed in this Committee to ensure consistency in the approach as regards feed and food.

Application of Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes

Following the request of a delegation the Commission representative clarified the provisions

- The Regulation applies as from 1 July 2017. This means that from 1 July 207 only detoxification processes which has been assessed and concluded by the European Food Safety Authority (EFSA) that the detoxification process complies with the acceptability criteria established in the Regulation, can be used for the detoxification of feed in authorised establishments.

A transitional measure is foreseen for:

- the detoxification processes for which EFSA has favourably concluded the assessment of the detoxification process but the procedure to authorise the establishment to perform the detoxification process is not finalised by 1 July 2017;
- the detoxification processes for which the necessary information was provided to the Commission before 1 July 2016 but EFSA has not finalised the assessment by 1 July 2017.

In both situations the detoxification process can be continued to be applied after 1 July 2017 awaiting the decision of the competent authority as regards the acceptability of the application of the detoxification process in the relevant establishment.

The representative of the Commission indicated to regularly update the delegations in the Committee on the progress of the application of this Regulation in order to ensure a smooth transition when the Regulation enters into application on 1 July 2017.

A.06 Feed marketing Regulation (EC) N° 767/2009.

A.06.1. Directive 2008/38/EC establishing the list of intended uses as particular nutritional purposes - state of play of pending evaluations and new applications

A Commission representative gave an update on the ongoing assessments. Several applicants will be asked to deliver supplementary information.

A.06.2. Revision of Annex IV, VI and VII (labelling provisions)

Further progress was made on the new texts for Annexes VI and VII, mainly on the quantitative labelling of the additives. The proposals for the revision of the labelling tolerances in Annex IV from one Member State were discussed. Further clarification is needed to better understand how the new values were calculated. The Committee will come back on the issue.

A.06.3. Endorsement of the COPA-COGECA/FEFAC Code of Good labelling practices for compound feed for food producing animals

The Regulation (EC) No 767/2009/EC provides for the establishment of a Code of Good Labelling Practice for compound feed for food producing animals to improve the appropriateness of labelling and in particular to include provisions on voluntary labelling aspects and claims. The Code should allow a harmonised approach concerning the interpretations of the labelling rules throughout the 28 Member States.

A Commission representative explained the newly revised version of the Code. One additional clarification was suggested in Annex IV on the disclosure of information on request of the purchaser.

The Commission representative concluded that the Committee agreed unanimously on the complete text as amended. He stressed that its dissemination to the control authorities is now crucial in order to allow a harmonised application of the agreed text. The Title and the References of the Code will be published in part C of the Official Journal of the EU. The authors will be invited to translate the Code into other Union languages.

A.06.4. Discussion of the draft revision of the F.E.D.I.A.F. Code of Good labelling practices for pet food

The revised version of the Code was shortly discussed. The Committee will come back on the issue once Member States had more time for a proper scrutiny.

A.06.5. Third amendment of the EU Catalogue of feed materials (Regulation (EU) N° 68/2013)

The Committee discussed the entries for invertebrates, a molasses high in betaine and the amended chapter 12. The feed chain task force will be asked to clarify several issues.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the provisional authorisation of a preparation of formaldehyde as a feed additive for chickens for fattening, laying hens, piglets (weaned) and pigs for fattening.

A representative of the Commission informed the Committee that the formal redrafting of the text of the draft Implementing Regulation for legal clarity purpose is being finalised. The revised version of the draft will be submitted to the Committee before its next meeting.

An exchange of views took place.

The Swedish delegation made the following statement:

"Opinion on the approval of formaldehyde as a feed additive.

Sweden wants to underline the need to do what is possible to avoid that feed and food is contaminated with salmonella. For that reason Sweden supported the creation of the new functional group "hygiene condition enhancers".

Sweden is also seriously concerned about the worker safety when using the substance formaldehyde as a feed additive.

However, the industry need to be able to adapt to the new situation and in the waiting for the formal approval of other products in the newly created functional group hygiene condition enhancers, Sweden accepts this product with the restricted use and short approval period of three years."

Vote postponed

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 and endo-1,3(4)-beta-glucanase produced by Trichoderma reesei (ATCC SD-2106) as a feed additive for lactating sows and minor porcine species (holder of authorisation Danisco (UK) Ltd).

This Regulation is related to an authorisation of this enzyme as zootechnical additive. A discussion took place.

Vote taken: Unanimous in favour.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of

ammonium chloride as a feed additive for ruminant other than lambs for fattening and cats and dogs (holder of the authorisation Latochema Co. Ltd).

This Regulation is related to an authorisation of this substance as zootechnical additive.

A discussion took place.

Vote taken: Unanimous in favour.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate, Zinc chelate of protein hydrolysates, Zinc chelate of glycine hydrate (solid) and Zinc chelate of glycine hydrate (liquid) as feed additives for all animal species and amending Regulations (EC) No 1334/2003, (EC) No 479/2006, (EU) No 335/2010 and Implementing Regulations (EU) No 991/2012 and (EU) No 636/2013.

The draft Implementing Regulation aims to authorise nine compounds of zinc and to establish reduced zinc contents in complete feed. A discussion took place on the analytical methods for the zinc chelates and the approach concerning the new maximum contents.

France made the following declaration:

"Contrairement aux premiers projets des textes d'autorisations des composés de zinc, aucune information sur des teneurs en zinc recommandées par l'ESFA ni sur les bénéfices d'utilisation des phytases conformément aux conclusions de l'avis de l'EFSA (EFSA Journal 2014;12(5):3668) n'apparait dans les textes proposés au vote à ce comité. En conséquence la délégation française s'abstient".

Non-official translation:

"Unlike the initial draft texts of authorisations of zinc compounds, no information on levels of zinc recommended by EFSA nor on profits from the use of phytase in accordance with the conclusions of the EFSA opinion (EFSA Journal 2014; 12(5): 3668) does not appear in the texts put to the vote in the Committee. Accordingly the French delegation abstained".

The collection of new scientific data about the physiological needs of the different animal species will be closely observed by the Commission Services and whenever sufficient evidence is available, the European Food Safety Authority will be requested to deliver an opinion concerning a further reduction of the zinc levels in complete feed.

Furthermore, it was concluded that the producers of the chelates shall develop analytical methods to prove that the zinc is chelated and only in small quantities present in inorganic form. Such methods should be sent to the EU Reference Laboratory for feed additives https://ec.europa.eu/jrc/en/eurl/feed-additives/

for validation. For those additives where the Fourier Transformed Infrared (FTIR) spectroscopy is used to prove chelation, producers should send to the EURL product matching standards with known chelate degree.

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 zinc bislysinate as a feed additive for all animal species.

The draft Implementing Regulation aims to authorise a new compound of zinc with the newly established zinc contents in complete feed. A brief discussion took place.

France made the following declaration:

"Contrairement aux premiers projets des textes d'autorisations des composés de zinc, aucune information sur des teneurs en zinc recommandées par l'ESFA ni sur les bénéfices d'utilisation des phytases conformément aux conclusions de l'avis de l'EFSA (EFSA Journal 2014;12(5):3668) n'apparait dans les textes proposés au vote à ce comité. En conséquence la délégation française s'abstient".

Non-official translation:

"Unlike the initial draft texts of authorisations of zinc compounds, no information on levels of zinc recommended by EFSA nor on profits from the use of phytase in accordance with the conclusions of the EFSA opinion (EFSA Journal 2014; 12(5): 3668) does not appear in the texts put to the vote in the Committee. Accordingly the French delegation abstained".

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 L-Arginine produced by *Corynebacterium glutamicum* (KCTC 10423BP) as a feed additive for all animal species.

The draft Implementing Regulation aims to authorise a new manufacturing strain for L-Arginine. A brief discussion took place.

Vote taken: Unanimous in favour.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of butan-1-ol, hexan-1-ol, octan-1-ol, nonan-1-ol, dodecan-1-ol, heptan-1-ol, decan-1-ol, pentan-1-ol, ethanol, acetaldehyde, propanal, butanal, pentanal, hexanal, octanal, decanal, dodecanal, nonanal, heptanal, undecanal, 1,1-diethoxyethane, formic acid, acetic acid, propionic acid, valeric acid, hexanoic acid, octanoic acid,

decanoic acid, dodecanoic acid, oleic acid, hexadecanoic acid, tetradecanoic acid, heptanoic acid, nonanoic acid, ethyl acetate, propyl acetate, butyl acetate, hexyl acetate, octyl acetate, nonyl acetate, decyl acetate, dodecyl acetate, heptyl acetate, methyl acetate, methyl butyrate, butyl butyrate, pentyl butyrate, hexyl butyrate, octyl butyrate, ethyl decanoate, ethyl hexanoate, propyl hexanoate, pentyl hexanoate, hexyl hexanoate, methyl hexanoate, ethyl formate, ethyl dodecanoate, ethyl tetradecanoate, ethyl nonanoate, ethyl octanoate, ethyl propionate, methyl propionate, ethyl valerate, butyl valerate, ethyl hex-3-enoate, ethyl hexadecanoate, ethyl trans-2-butenoate, ethyl undecanoate, butyl isovalerate, hexyl isobutyrate, methyl 2-methylbutyrate, hexyl 2-methylbutyrate, triethyl citrate, hexyl isovalerate and methyl 2-methylvalerate as feed additives for all animal species (CDG 01).

The draft proposes to authorise certain flavourings as feed additives for all animal species.

A discussion took place.

Vote taken: Unanimous in favour.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of 2methylpropan-1-ol, isopentanol, 3,7-dimethyloctan-1-ol, 2-ethylhexan-1-ol, 2methylpropanal, 3-methylbutanal, 2-methylbutyraldehyde, 3-methylbutyric acid, 2-methylvaleric acid, 2-ethylbutyric acid, 2-methylbutyric methylheptanoic acid, 4-methylnonanoic acid, 4-methyloctanoic acid, isobutyl acetate, isobutyl butyrate, 3-methylbutyl hexanoate, 3-methylbutyl dodecanoate, 3-methylbutyl octanoate, 3-methylbutyl propionate, 3-methylbutyl formate, glyceryl tributyrate, isobutyl isobutyrate, isopentyl isobutyrate, isobutyl isovalerate, isopentyl 2-methylbutyrate, 2-methylbutyl isovalerate and 2methylbutyl butyrate as feed additives for all animal species (CDG 02).

The draft proposes to authorise certain flavourings as feed additives for all animal species.

A discussion took place.

Vote taken: Unanimous in favour.

M.01 A.O.B.

Refuse-derived fuels' or RDF.

United Kingdom provided an outline of concerns regarding 'refuse-derived fuels' or RDF, which is essentially household waste with the recyclable content removed. By a short presentation some concerns on lack of hygiene procedure during the storage and the transfers in the ports were raised. Member States were invited to share their experiences and possible solutions.