### EUROPEAN COMMISSION



HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2017)6113639

# SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 08 NOVEMBER 2017 - 10 NOVEMBER 2017 (Section Animal Nutrition)

CIRCABC Link: https://circabc.europa.eu/w/browse/58944e37-9e49-4410-ba3c-16c224e8a84b

- A.01 Feed Additives Applications under Regulation (EC) No 1831/2003 Art. 4 or 13
  This item was not discussed.
- A.02 Feed Additives Applications under Regulation (EC) No 1831/2003 Art. 9

A.02.1. Alterion NE® (Bacillus subtilis DSM 29784) as a feed additive for chickens for fattening and chickens reared for laying – Annex.

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

A.02.2. Levucell® SB (Saccharomyces cerevisiae CNCM 1-1079) as a feed additive for weaned piglets and sows – Annex and A.02.3. Levucell® SB (Saccharomyces cerevisiae CNCM 1-1079) as a feed additive for weaned piglets - Annex

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

A.02.4. Lactobacillus hilgardii CNCM 1-4785 as a silage additive for all animal species - Annex

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

A.02.5. Lactobacillus buchneri NRRL B-50733 as a silage additive for all animal species - Annex

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

A.02.6. Hostazym® X (endo-1,4-b-xy lañase) as a feed additive for carps - Annex

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

A.02.7. copper compounds (E4) for all animal species: Copper(II) diacetate monohydrate, Copper(II) carbonate dihydroxy monohydrate, Copper(II) chloride dehydrate, Copper(II) oxide, Copper(II) sulphate pentahydrate, Cupric chelate of amino acids, hydrate, Cupric chelate of glycine, hydrate (solid), Cupric chelate of glycine, hydrate (liquid) - Annex entry

The draft Annex entry reflects the EFSA recommendations for maximum contents in complete feed. Concerning the recommendation to drastically reduce the Cu content in feed for piglets, a stepwise approach is suggested which significantly would reduce the quantity of Cu in piglet feed without creating a big risk for increasing in exchange the use of antibiotics. Many Member States supported the idea of not immediately establishing the levels recommended by EFSA. This issue and the specific entries of the nine copper compounds will be further discussed in the next Committee.

## A.03 Implications for the National Reference Laboratories with the entering into force of the new controls Regulation (EU) No 625/2017.

This item was not discussed due to lack of time.

## A.04 Information about the status on the evaluation of 4-phenylbut-3-en-2-one and benzophenone (CDG 021).

This item was not discussed due to lack of time.

### A.05 Discussion on amendment of Regulation (EC) No 429/2008.

This item was not discussed.

## A.06 Issues related to Regulation (EC) No 183/2005 laying down requirements for feed hygiene.

A.06.1. 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. There seems to be agreement on most of the issues addressed in the document. Chapter regarding "registration of establishments" still needs further discussion, especially in the case of food retailers. It was agreed on sending written comments.

A.06.2. Exchange of views on measures for non-authorised additives intended for export.

This point was not discussed.

A.06.3. Guide to good practice for the manufacture of safe pet foods - FEDIAF.

The Commission's representative presented to the Committee the "guide to good practice for the manufacture of safe pet foods" from FEDIAF. Member States required extra time for the assessment of the document. It is envisaged to present the document to the next Committee for its endorsement.

### A.07 Feed marketing Regulation (EC) N° 767/2009.

A.07.1. Dietetic feed (Directive 2008/38/EC): state of play of pending evaluations, new applications and draft Regulation for repealing the Directive

The Commission's representative gave an update on the new and pending applications. Member States commented on the draft new Annex. A revised draft will be prepared for the next Committee.

A.07.2. Feed material classification: Butaphosphane, Macrogolglycerol ricinoleate (castor oil)

- The Commission's representative informed the Committee that Butaphosphane had entered the Register of Feed Materials. After a short discussion, it was concluded that Butaphosphane is not a feed material. As the two entries were notified by feed business operators in DE and the UK, these Member States were asked to contact those in order to induce the withdrawal.
- The listing of macrogolglycerol ricinoleate in the Register of Feed Materials pretends that it is castor oil. Indeed, the oil from pressing the seeds of Ricinus communis can be considered to be a feed material (castor oil). However, the product must be different from glyceryl polyethyleneglycol ricinoleate which is a technological feed additive belonging to the functional group "Emulsifying and stabilizing agents, thickeners and gelling agents". The Commission's representative informed the Committee that Directive 2002/32/EC establishes a maximum content for seeds and husks of Ricinus communis and their processed derivatives of 10 mg per kg compound feed. In case of need, a revision of this maximum content might be envisaged.
- One Member State raised a question regarding the status of polyethylene glycol (PEG) substances, more specifically the status of PEG 400 (with a molecular weight of approximately 400 g/mole). The Committee will come back on the issue.

A.07.3 Placing on the market of unauthorised feed materials: by-products from the production of amino acids produced with genetically modified micro-organisms.

The point was dealt together with point A.09.

### A.08 RASFF.

A.08.1 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 September 2017.

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

- cadmium in tuna fish meal from Portugal
- mercury in fish meal for the production of pet food from Spain
- arsenic and lead in complementary feed (zeolite) from Turkey
- arsenic in dimanganese chloride trihydroxide from the United States
- ragweed (Ambrosia spp) seeds in feed for parrots and in feed for pigeons from Netherlands.
- aflatoxins in groundnuts from United States and in peanuts from birdfeed from Tanzania
- free gossypol in cotton seeds from Benin
- Crotalaria in hay from the Netherlands.

Furthermore, the attention was drawn to the notification of a high level of finely grated packaging material in feed for piglets from France.

## A.09 Discussion on EFSA Opinions on nutritional value of dried killed bacterial biomasses from Escherichia coli (FERM BP-10942) [PT73 (TM)] and from Escherichia coli (FERM BP-10941) [PL73 2 (LM)] as feed materials for pigs, ruminants and salmonids.

The Commission's representative informed the Committee about the two EFSA opinions on the safety and nutritional value of dried killed bacterial biomasses from Escherichia coli (FERM BP-10942) [PT73 (TM)] and from Escherichia coli (FERM BP-10941) [PL73 (LM)] as feed materials for pigs, ruminants and salmonids, adopted by the FEEDAP Panel on 5 July 2017. He clarified that the two bacterial strains are genetically modified and therefore the two related applications were submitted under Regulation (EC) No 1829/2003. Whereas EFSA did not identify risks for human and animal health or the environment from the biomass regarding the genetic modification of the bacterial strains, it could not conclude on the safety for the consumer of products derived from animals receiving feed containing PT73 (TM) and PL73 (LM). The applicant for both authorisations informed the Commission of its intention to provide supplementary information. Such information would be further assessed by EFSA. It was clarified that the recommendation under point 6 of the EFSA opinions is not related to the genetic modification of the bacterial strains. With respect to this recommendation, the Commission Services announced to carefully examine available scientific evidence concerning the potential risk of similar non-genetically modified biomasses.

#### A.10 Undesirable substances.

A.10.1 Further exchange of views on nitrates and nitrites in feed

An update was given as regards the progress on the different action points as discussed and agreed at previous meetings of the Committee.

A.10.2 Further exchange of views on the different topics for possible future amendment of the annexes of Commission Directive 2002/32/EC (arsenic in peat and leonardite, nitrites, gossypol, definition of trace amounts, dioxins and *p*-phenetidine)

An update was provided on the different topics with concrete suggestions for arsenic in peat and lenonardite, free gossypol in cottonseed and dioxins and PCBs in functional group of binders and anti-caking agents. The Commission's representative indicated to integrate these suggestions in a legislative text for discussion at a next meeting.

The Commission's representative informed the Committee that the authorisation holder of dimanganese chloride trihydroxide has requested to increase the maximum level of arsenic in dimanganese chloride trihydroxide from the current 30 mg/kg to 100 mg/kg (in line with the maximum level for arsenic in manganous oxide). This issue will be discussed in more detail at a next meeting of the Standing Committee.

### A.10.3 Update on assessment by EFSA on detoxification processes

The Committee was informed that EFSA's CONTAM Panel has adopted at its 86th meeting in September 2017 an opinion as regards an application of the decontamination of linseed for hydrocyanic acid. For the other 4 applications additional information was requested to the applicant to enable completion of the assessment. It is expected that the assessment of 3 of these applications shall be finalised by the end of 2017/early 2018 while for one application the assessment is expected to be finalised only later in 2018.

A.10.4 Follow-up to recent EFSA opinions/statements. Undesirable substances of relevance for future monitoring in feed.

Reference was made to recent opinions from EFSA of relevance for feed (for pyrrolizdine alkaloids it relates to the pyrrolizidine alkaloids of relevance for monitoring):

- risks for animal health related to the presence of zearalenone and its modified forms in feed
- risks for human health related to the presence of pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements
- risks to human and animal health related to the presence of deoxynivalenol and its acetylated and modified forms in food and feed.

The Committee was also informed by the Commission's representative as regards the organisation in the first half of 2018 of a Fusarium forum (presence of competent authorities and relevant EU professional stakeholder organisations) to discuss the follow up of the EFSA opinion on deoxynivalenol and the follow up to Commission Recommendation 2013/165/EU as regards T-2 and HT-2 toxin.

The document providing an overview of undesirable substances for which it is expected that possible regulatory measures might be discussed in the near future is still under preparation and not available yet. This information would be useful for the laboratories to develop the methods of analysis therefore if needed and for competent authorities to take this into account in future surveys to collect the necessary monitoring results in support of risk assessment and/or the discussion on possible risk management measures.

A.10.5 Other issues (more details to follow).

Tetrahydrocannabinol in hemp derived products: the Commission representative informed the Committee to expect to be able to provide the requested information at the next meeting of the Committee.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of 2,3-diethylpyrazine, 2,5 or 6-methoxy-3-methylpyrazine, 2-acetyl-3-ethylpyrazine, diethyl-5-methylpyrazine, 2-(sec-butyl)-3-methoxypyrazine, 2-ethyl-3-methoxypyrazine, 5,6,7,8-tetrahydroquinoxaline, 2-ethylpyrazine and 5-methylquinoxaline as feed additives for all animal species (CDG 024).

The draft Regulation proposes the authorisation of some flavourings of the chemical group 024 as feed additives for all animal species. 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 methyl 2-furoate,bis-(2-methyl-3-furyl) disulphide,furfural, furfuryl alcohol, furanmethanethiol, S-furfuryl acetothioate, difurfuryl disulphide, methyl furfuryl sulphide,2-methylfuran-3-thiol, methyl furfuryl disulphide, methyl 2-methyl-3-furyl disulphide and furfuryl acetate as feed additives for all animal species (CDG 014).

The draft Regulation proposes the authorisation of some flavourings of the chemical group 014 as feed additives for all animal species. A discussion took place.

**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 linalool oxide as a feed additive for all animal species (CDG 013).

The draft Regulation proposes the authorisation of the flavouring linalool oxide belonging to the chemical group 013 as a feed additive for all animal species except

fish. The applicant withdrew the authorisation for this species. A discussion took place.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of menthol, d-carvone, menthyl acetate, d,l-isomenthone, methyl-2-cyclopenten-1-one, 3,5,5-trimethylcyclohex-2-en-1-one, d-fenchone, fenchyl alcohol, carvyl acetate, dihydrocarvyl acetate and fenchyl acetate as feed additives for all animal species (CDG 08).

The draft Regulation proposes the authorisation of some flavourings of the chemical groups 08 as feed additives for all animal species. The 3 methyl-2-cyclopenten-1-one was not included in the authorisation as there was an error. This additive was replaced by the correct additive: 3-methyl-2-(pent-2(cis)-enyl)cyclopent-2-en-1-one (FLAVIS 07.094). A discussion took place.

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 taurine, beta-alanine, L-alanine, L-arginine, L-aspartic acid, L-histidine, D,L-isoleucine, L-leucine, L-phenylalanine, L-proline, D,L-serine, L-tyrosine, L-methionine, L-valine, L-cysteine, L-cysteine hydrochloride monohydrate, glycine, monosodium glutamate and L-glutamic acid as feed additives for all animal species (CDG 034).

The draft Regulation proposes the authorisation of some flavourings belonging to the chemical groups 034 as feed additives for all animal species. As L-cysteine hydrochloride monohydrate was already authorised as flavouring for cats and dogs the authorisation for this amino acid was authorised for all species except cats and dogs. 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 2,4,5-trimethylthiazole, 2-isobutylthiazole, 5-(2-hydroxyethyl)-4-methylthiazole, 2,4, 5-trimethylthiazole, 2-acetylthiazole, 2-ethyl-4- methylthiazole, 5,6-dihydro-2,4,6,tris(2-methylpropyl)4H-1,3,5-dithiazine and thiamine hydrochloride as feed additives for all animal species (CDG 029).

The draft Regulation proposes the authorisation of some flavourings of the chemical group 014 as feed additives for all animal species. A discussion took place.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of preparations of lecithins, lecithins hydrolysed and lecithins de-oiled as feed additives for all animal species and amending Regulation (EU) No 2017/1007.

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

Vote taken: Unanimity.

B.08 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 5750) and Bacillus licheniformis DSM 5749 as a feed additive for suckling piglets (holder of authorisation Chr.Hansen A/S).

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

Vote taken: Unanimity.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of Pediococcus acidilactici CNCM MA 18/5M as a feed additive for pigs for fattening, minor porcine species (weaned) and for fattening, chickens for fattening, minor poultry species for fattening and minor poultry species for laying, the authorisation of that feed additive for use in water for drinking and amending Regulations (EC) No 2036/2005, (EC) No 1200/2005 and (EU) No 413/2013 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS).

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

Vote taken: Unanimity.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of Bacillus subtilis ATCC PTA-6737 as a feed additive for sows (holder of authorisation Kemin Europa N.V).

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

Vote taken: Unanimity.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a new use of 6-phytase (EC 3.1.3.26) produced by Komagataella pastoris (DSM 23036) as a feed additive for fish (holder of authorisation Huvepharma EOOD).

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

Vote taken: Unanimity.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a new use of the preparation of Lactobacillus acidophilus (CECT 4529) as a feed additive for chicken for fattening (holder of the authorisation Centro Sperimentale del Latte).

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

**Vote taken:** Unanimity.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a new use of the preparation of Bacillus subtilis (DSM 15544) as a feed additive for sows, suckling piglets and dogs (holder of the authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office).

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

**Vote taken:** Unanimity.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) 2016/329 as regards the name of the holder of the authorisation of 6-phytase as a feed additive for all avian species and for weaned piglets, pigs for fattening.

The draft Regulation refers to a changing of authorisation holder. A discussion took place.

Vote taken: Unanimity.

B.15 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of

## glycine hydrate as feed additives for all animal species and of Iron dextran as feed additive for piglets.

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

With respect to the total iron content of the complete feed, the following footnote had been established: "The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed." The methods of analysis for controlling the iron content in the feed have been standardised specifically for the feed matrix. They measure total iron, i.e. also the fraction of total iron that is considered as inert. Alternative methods that do not measure inert iron and are suitable for official control have not been identified and therefore not evaluated by the EURL. As there are no analytical methods for the inert iron, the official controls should screen the composition of the feed based on the documentation provided to check whether a significant amount of inert iron is present. By subtraction of this fraction from the total analysed iron, the respective value should be checked for compliance with the maximum content established in the authorisation act.

The German Delegation made the following declaration: "Die deutsche Delegation kann dem Gesamtvorschlag zur Zulassung von verschiedenen Eisenverbindungen zustimmen, weist aber darauf hin, dass sich die vorgesehenen Verwendungsbedingungen für die neu zuzulassende Spurenelementverbindung "3b110, Eisendextran 10 %" von einem in der Bundesrepublik Deutschland zugelassenem wirkstoffgleichem Tierarzneimittel nicht maßgeblich unterscheiden."

Vote taken: Unanimity.

## B.16 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Regulation (EC) No 900/2009 as regards the characterisation of selenomethionine produced by Saccharomyces cerevisiae CNCM I-3399.

The draft Regulation concerns the characterisation of selenomethionine produced by Saccharomyces cerevisiae CNCM 1-3399.

The Delegation of the UK made the following declaration: "In July 2014, the UK abstained on the feed additive authorisation of seleno-methionine following the statutory reduction of a maximum content for the organic form to 0.2 mg/kg selenium in complete feed. Prior to this reduction, organic forms of selenium authorised as feed additives had a maximum content of 0.5 mg/kg. Work undertaken on behalf of the United Kingdom Government has suggested that a significant proportion of our population is under-exposed to dietary selenium, a trace element that is essential for human health. In view of the possibility that the low maximum limit for this organic form of selenium could result in lower levels of this essential trace element in the diet of consumers, the United Kingdom maintains its principle in not supporting the European Commission's proposal for point B.16 and therefore abstained in the decision taken for this item."

Vote taken: Favourable opinion.

## B.17 Exchange of views and possible opinion of the Committee on a draft Commission Recommendation establishing guidelines for the use of former foodstuffs as feed.

A considerably revised draft for EU guidelines was presented. The delegations appreciated the revision and constructively commented on the text. The Commission's representative informed the Committee that the internal discussions within the Commission Services will be finalised soon. Moreover, he announced that the Commission will revise the draft guidelines considering the comments received by the other Services and the Member States in the margins of this meeting in order to finalise the document in form of a Commission Notice.

### Vote postponed

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of endo-1,4-b-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (BCCM/MUCL 49755) as a feed additive for pigs for fattening (holder of authorisation Berg and Schmidt GmbH Co. KG).

The draft Regulation refers to an authorisation as zootechnical additive. Following the discussion, the draft Regulation will be submitted for the vote in the next meeting.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation on the denial of authorisation of formaldehyde as a feed additive belonging to the functional groups of preservatives and hygiene condition enhancers.

The Commission's representative presented a new version of the preliminary draft measure. It was highlighted that the current version is still subject to re-drafting in the context of internal consultations.

Delegations were requested to communicate the Member States' position, in so far as it may already have been defined, on the proposed approach as regards the measure to be taken.

An exchange of views took place.

A new version of the draft measure will be prepared and communicated to the Committee as soon as possible.

#### M.01 A.O.B.

The Commission's representative presented to the Committee the issue of the interim measures for the imports of feed established in Article 24 of Regulation (EC) 183/2005 laying down requirements for feed hygiene. It was explained that this may be the moment to reflect on the implementation of the requirements of Article 23 of

Regulation (EC) 183/2005 regarding imports of non-EU countries. It was requested to Member States to provide information of the non-EU countries which are currently exporting feed products to the EU. A document will be prepared and sent to the Member States in order to collect the information.