

Scientific Panel on Additives and Products or Substances used in Animal Feed

Minutes of the 136th Plenary meeting

Held on 27-29 November 2018, Parma (Italy)

(Agreed by written procedure on 5 December 2018)

Participants

■ Panel Members

Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen¹, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente², Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Roberto Villa and Ruud Woutersen.

■ Hearing Experts:

N/A

■ European Commission and/or Member States representatives:

Marta Ponghellini (DG SANTE)

■ EFSA:

FEED Unit: Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Lucilla Gregoretti, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Niovi Kordali, Paola Manini, Elisa Pettenati, Fabiola Pizzo, Jordi Tarrés-Call, Manuela Tiramani and Maria Vittoria Vettori.

ALPHA Unit: Frank Verdonk³

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Yolanda Sanz. The Chair welcomed also Fabiola Pizzo as Scientific Officer and Elisa Pettenati as trainee in the Feed Unit.

¹ Participated via webconference on 29/11/2018

² Participated via webconference

³ Attended on 27-28/11/2018

2. Adoption of agenda

The agenda was adopted with the addition of Lantharenol® (Lanthanum carbonate octahydrate) for cats ([EFSA-Q-2017-00288](#)).

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Report on the written procedures since 135th Plenary meeting

The minutes of the 135th Plenary meeting held on 2-4 October 2018 were agreed by written procedure on 8 October 2018.⁶

5. Scientific outputs submitted for discussion and/or possible adoption

5.1. Riboflavin sodium phosphate for all animal species ([EFSA-Q-2012-00955](#))

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of riboflavin sodium phosphate as a nutritional additive for all animal species.

The draft opinion was discussed, focusing mainly on the characterisation of the additive and its safety for the target species, consumer, user and environment and on its efficacy. The Panel unanimously adopted the opinion.

5.2. Chemically defined flavourings from Chemical Group 20 - aliphatic and aromatic mono- and di-thiols and mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups when used as flavourings: 8-mercapto-p-methan-3-one [12.038], p-menth-1-ene-8-thiol [12.085] for all animal species and categories ([EFSA-Q-2013-00325](#))

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of 8-mercapto-p-methan-3-one and

⁴ [Policy on Independence](#)

⁵ [Competing Interest Management](#)

⁶ http://www.efsa.europa.eu/sites/default/files/event/feedap181002_web_m.pdf

p-menth-1-ene-8-thiol as sensory additives for all animal species and categories.

The draft opinion was discussed, focusing mainly on the characterisation of the additive and its safety for the target species, consumer, user and environment and on its efficacy. The Panel unanimously adopted the opinion.

5.3. Deccox[®] (decoquinat) for chickens for fattening ([EFSA-Q-2013-00705](#))

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Deccox[®] as a coccidiostat for chickens for fattening.

The draft opinion was discussed. Discussion focussed mainly on the safety of the additive for the target animals, the environment and its efficacy. The Panel unanimously adopted the opinion.

5.4. Ethoxyquin (6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline) for all animal species ([EFSA-Q-2016-00267](#), [EFSA-Q-2018-00372](#), [EFSA-Q-2018-00013](#))

EFSA informed on the status of these applications.

5.5. Concentrated liquid L-lysine (base), L-lysine monohydrochloride and L-lysine sulfate produced using different strains of *Corynebacterium glutamicum* for all animal species ([EFSA-Q-2016-00391](#))

This question refers to the inconclusive opinion under Art. 29 Regulation (EC) No 178/2002 of Concentrated liquid L-lysine (base), L-lysine monohydrochloride and L-lysine sulfate produced using different strains of *Corynebacterium glutamicum* as nutritional additives for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation and the safety of the production strains and of the additives. The Panel unanimously adopted the opinion.

5.6. ALKOSEL (selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397) for all animal species ([EFSA-Q-2016-00455](#))

This question refers to the renewal of authorisation under Article 14 of Regulation (EC) No 1831/2003 of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as a nutritional additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation and the safety of the additive. The Panel unanimously adopted the opinion.

5.7. *Lactobacillus reuteri* NBF 1 (*L. reuteri* DSM 32203) for dogs ([EFSA-Q-2017-00049](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Lactobacillus reuteri* NBF 1 as a zootechnical additive for dogs.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, the safety and its efficacy. The Panel unanimously adopted the opinion.

5.8. *Lactobacillus reuteri* NBF 2 (*L. reuteri* DSM 32264) for cats ([EFSA-Q-2017-00050](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Lactobacillus reuteri* NBF 2 as a zootechnical additive for cats.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, its safety and its efficacy. The Panel unanimously adopted the opinion.

5.9. Benzoic acid for weaned piglets and pigs for fattening ([EFSA-Q-2017-00103](#), [EFSA-Q-2018-00276](#))

These questions refer to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of benzoic acid as a technological additive for weaned piglets and pigs for fattening.

The draft opinion was discussed. Discussion focussed mainly on the safety of the additive for the target animals and its efficacy. The Panel unanimously adopted the opinion.

5.10. Lantharenol® (Lanthanum carbonate octahydrate) for cats ([EFSA-Q-2017-00288](#))

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Lantharenol® as a zootechnical additive for cats. Discussion focussed mainly on the safety of the additive for the target animals. The Panel unanimously adopted the opinion.

5.11. L-Valine produced by fermentation with *Corynebacterium glutamicum* KCCM 11201P for all animal species ([EFSA-Q-2017-00483](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-Valine produced by fermentation with

Corynebacterium glutamicum KCCM 11201P as a nutritional additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive and its safety and efficacy. The Panel unanimously adopted the opinion.

5.12. L-lysine monohydrochloride and concentrated liquid L-lysine for all animal species ([EFSA-Q-2017-00501](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-lysine monohydrochloride and concentrated liquid L-lysine as nutritional additives for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the safety of the additive. The Panel unanimously adopted the opinion.

5.13. B-Act® (*Bacillus licheniformis* DSM 28710) for turkeys for fattening, turkeys reared for breeding and minor poultry species ([EFSA-Q-2017-00524](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of B-Act® as a zootechnical additive for turkeys for fattening, turkeys reared for breeding and minor poultry species.

The draft opinion was discussed. Discussion focussed on the safety of the additive for the target species and its efficacy. The Panel unanimously adopted the opinion.

5.14. Preparation of 3-phytase produced by fermentation of a genetically modified strain of *Komagataella phaffii* chickens for fattening or reared for laying, laying hens and minor poultry species ([EFSA-Q-2017-00650](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of preparation of 3-phytase produced by fermentation of a genetically modified strain of *Komagataella phaffii* as a zootechnical additive for chickens for fattening or reared for laying, laying hens and minor poultry species.

The draft opinion was discussed. Discussion focussed on the characterisation of the additive, its safety and efficacy. The Panel unanimously adopted the opinion.

5.15. Cassia gum for dogs and cats ([EFSA-Q-2018-00124](#))

The European Commission asked EFSA to deliver an opinion on the safety of cassia gum as a technological additive for cats and dogs based on the additional information submitted by the applicant.

The draft opinion was discussed. Discussion focussed mainly on the safety of the additive. The Panel unanimously adopted the opinion.

5.16. HOSTAZYM® X (endo-1,4-beta-xylanase) as a feed additive for rabbits for fattening ([EFSA-Q-2018-00420](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of HOSTAZYM® X as a zootechnical additive for rabbits for fattening.

The draft opinion was discussed. Discussion focussed mainly on the safety of the additive for the target species and its efficacy. The Panel unanimously adopted the opinion.

5.17. Levucell SB 20, 10 ME, 10 ME Titan (*Saccharomyces cerevisiae* CNCM I-1079) for piglets (suckling), pigs for fattening, minor pig categories and minor porcine species ([EFSA-Q-2018-00473](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Levucell as a zootechnical additive for piglets (suckling), pigs for fattening, minor pig categories and minor porcine species.

The draft opinion was discussed. Discussion focussed mainly on the safety of the additive and its efficacy. The Panel unanimously adopted the opinion.

5.18. Vitamin D₃ as feed additive for salmonids ([EFSA-Q-2018-00511](#))

The European Commission requested EFSA to deliver an opinion on the safety of Vitamin D₃ for the environment when used as a nutritional additive in feed for salmonids, based on the additional data submitted by the Norwegian Food Safety Authority.

The draft opinion was discussed. Discussion focussed on the safety of the additive for the environment. The Panel unanimously adopted the opinion.

6. New mandates

6.1. New applications under Regulation (EC) No 1831/2003 since the previous meeting

The Commission has forwarded to EFSA the following new applications of feed additives seeking authorisation under Regulation (EC) No 1831/2003 since the last Plenary meeting. These applications were presented to the Panel:

EFSA-Q Number	Subject
EFSA-Q-2018-00758	Ferric citrate chelate for piglets (weaned, suckling) and minor porcine species
EFSA-Q-2018-0076	AveMix® XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for chickens for fattening
EFSA-Q-2018-00782	L-histidine monohydrochloride monohydrate using <i>Escherichia coli</i> NITE BP-02526 for all animal species
EFSA-Q-2018-00824	ECONASE® XT (endo-1,4-beta-xylanase) for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkey reared for breeding
EFSA-Q-2018-00893	Yea-Sacc® (<i>Saccharomyces cerevisiae</i> CBS 493.94) for horses
EFSA-Q-2018-00815	Gellan gum for cats and dogs
EFSA-Q-2018-00908	Selenium enriched yeast (<i>Saccharomyces cerevisiae</i> CNCM I-3399) for all animal species

6.2. Valid applications under Regulation (EC) No 1831/2003 since the previous meeting

Applications considered valid for the start of the assessment:

EFSA-Q-Number	Subject	Valid on
EFSA-Q-2018-00507	L-lysine monohydrochloride and concentrated liquid L-lysine (base) for all animal species	01/10/2018
EFSA-Q-2018-00552	L-cysteine monohydrochloride monohydrate by fermentation with <i>Escherichia coli</i> KCCM 80180 and <i>Escherichia coli</i> KCCM 80181 for all animal species	19/10/2018
EFSA-Q-2018-00612	L-Arginine with <i>Corynebacterium glutamicum</i> KCCM 80182 for all animal species	10/10/2018
EFSA-Q-2018-00630	Levucell SC (<i>Saccharomyces cerevisiae</i> CNCM I-1077) for calves and other (pseudo)ruminants species at the corresponding developmental stage	25/09/2018
EFSA-Q-2018-00631	Levucell SB (<i>Saccharomyces cerevisiae</i> CNCM I-1079) for turkeys for fattening	25/09/2018
EFSA-Q-2018-00632	Bactocell (<i>Pediococcus acidilactici</i> CNCM MA 18/5M) for all fish (including ornamental fish) and all crustaceans (including ornamental crustaceans)	25/09/2018
EFSA-Q-2018-00641	Bactocell (<i>Pediococcus acidilactici</i> CNCM MA 18/5M) for all birds/avian species and categories and all growing pig/suidae species and categories	02/10/2018 16/10/2018
EFSA-Q-2018-00678	ZM16 (<i>Bacillus amyloliquefaciens</i> DSM25840) for pigs for fattening, sows, piglets (weaned, suckling) and other minor porcine species	16/10/2018
EFSA-Q-2018-00679	EB15 (<i>Bacillus subtilis</i> DSM 25841) for pigs for fattening, sows, piglets (weaned, suckling) and other minor porcine species	13/11/2018
EFSA-Q-2018-00647	Bonvital (<i>Enterococcus faecium</i> DSM 7134) for sows for reproduction	19/11/2018
EFSA-Q-2018-00693	L-glutamine produced using strain <i>Corynebacterium glutamicum</i> NITE BP-02524 for all animal species	25/09/2018
EFSA-Q-2018-00668	BioPlus® 2B (<i>Bacillus licheniformis</i> DSM 5749 and <i>Bacillus subtilis</i> DSM 5750) for turkeys for fattening	09/10/2018

EFSA-Q-2018-00677	Calsporin® (<i>Bacillus subtilis</i> C-3102, DSM 15544) for all poultry species	12/10/2018
EFSA-Q-2018-00689	Zinc chelate of ethylenediamine (ZnEDA) for all animal species	19/10/2018
EFSA-Q-2018-00758	Ferric citrate chelate for piglets (weaned, suckling) and minor porcine species	15/11/2018
EFSA-Q-2018-00712	L-Valine produced by fermentation with <i>Escherichia coli</i> K12 KCCM 80159 for all animal species	30/10/2018
EFSA-Q-2018-00713	Manganese chelate of ethylenediamine (MnEDA) for all animal species	30/10/2018
EFSA-Q-2018-00782	L-histidine monohydrochloride monohydrate using <i>Escherichia coli</i> NITE BP-02526 for all animal species	22/11/2018

These applications were assigned to the respective working groups.

6.3. New questions under Regulation (EC) No 178/2002 since the previous meeting

EFSA-Q-Number	Subject
EFSA-Q-2018-00798	Fra® Octazyme C Dry (alpha-galactosidase, alpha-amylase, endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, mannan-endo-1,4-beta-mannosidase, pectinase, protease, endo-1,4-beta-xylanase) for chickens for fattening and weaned piglets

These questions were assigned to the respective working groups.

7. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

7.1. Scientific Committee

- a) The Panel was informed that the Scientific Committee has adopted the Statement on the genotoxicity assessment of chemical mixtures on 22 November 2018. The approach described in the document for fully defined mixtures and for mixtures containing a substantial fraction of unidentified components was presented. The relevance and the applicability of the statement to the assessment of feed additives was discussed.

7.2. EFSA

- a) The Panel was informed on the ad-hoc meeting with stakeholders, which took place in Brussels on 20 November 2018 to discuss some aspects of the guidance on the characterisation of microorganisms used as feed additives or as production organisms. The meeting took place upon request from three associations AMFEP, FEFANA and EUROPABIO. The aspects discussed during the meeting included i) the use of the whole genome sequencing analysis

in the risk assessment of microorganisms, ii) the cut-off values set for the minimum inhibitory concentration of antibiotics and iii) the methodology to be followed for the determination of the presence of DNA in additives obtained by fermentation. The meeting was a good opportunity for open dialogue and discussion.

- b) The Panel was also informed on the composition of the working groups.
- c) The Panel was informed about the EFSA journal guidelines to avoid plagiarism.
- d) The Panel was also informed that the EFSA Journal is now indexed in the SCOPUS database.

7.3. European Commission

Not discussed

8. Other scientific topics for information and/or discussion

- a) The Panel was informed on the outcome of the public consultation of the draft guidance for the assessment of the safety of feed additives for the environment. The comments will be revised and considered in the revised draft that will be presented for adoption in one of the coming plenary meetings.
- b) Discussion took place on the acceptability of efficacy studies in the context of an application for a zootechnical additive.

9. Any other business

Not discussed