

Scientific Panel on Additives and Products or Substances used in Animal Feed
Minutes of the 112th plenary meeting
Held on 16-18 June 2015, Parma
(Agreed by written procedure on 26 June 2015)

These minutes replace an earlier version following an editorial amendment that does not affect their contents or outcome. To avoid confusion, the original version has been removed from the EFSA website.

Participants

• Panel Members:

Gabriele Aquilina, Vasileios Bampidis, Maria De Lourdes Bastos, Lucio Guido Costa, Gerhard Flachowsky, Mikolaj Antoni Gralak, Christer Hogstrand,¹ Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Fernando Ramos, Derek Renshaw, Guido Rychen, Maria Saarela,² Kristen Sejrsen, Patrick van Beelen, John Wallace and Johannes Westendorf.

• Hearing Experts:³

- N/A

• European Commission and/or Member States representatives:

- N/A

• EFSA:

- **FEED Unit:** Manuela Tiramani, Jaume Galobart, Jaime Aguilera, Montserrat Anguita, Rosella Brozzi, Matteo Innocenti, Oriol Ribó and Jordi Tarrés-Call.

• Observers

- Pasquale Mari⁴

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted after removal of the item "Vitamin B2 (riboflavin and riboflavin 5'-phosphate ester monosodium salt) (Riboflavin Universal; ROVIMIX[®] B2 80-SD; Riboflavin 5'- Phosphate Sodium) for all animal species (EFSA-Q-2010-01319)".

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director implementing this Policy on Declarations of Interest,⁶ EFSA screened the Annual Declaration of Interest and the

¹ Present only on 16 and 17 June.

² Present only on 16 and 17 June.

³ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

⁴ Present only on 16 June. Pasquale Mari is a consultant working on the EFSA project aimed at reviewing the independence policy. He randomly chose a panel and attended it to witness the practical panel dynamics amongst the scientists and the decision making process.

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Specific Declaration of Interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 111th Plenary meeting held on 28-30 April 2015

The minutes of the 111th Plenary meeting were reviewed and agreed.⁷

5. Scientific outputs submitted for discussion and possible adoption⁸

5.1. Lactic acid and calcium lactate for all animal species (EFSA-Q-2010-01221)

Not discussed due to lack of time.

5.2. Lignosulphonate for all animal species (EFSA-Q-2010-01283)

A member of the working group (WG) presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of lignosulphonate as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for chickens for fattening, laying hens, pigs for fattening and cattle for fattening at a maximum concentration of 10 000 mg/kg complete feed but a margin of safety could not be established. The Panel also concluded that while the additive is safe for the consumer, it is hazardous by inhalation and could not conclude on the safety for the environment. Finally, the Panel considered that the additive is efficacious as a pellet binder.

The opinion was adopted.

5.3. Kemzyme Plus Liquid (endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, alpha-amylase and endo-1,4-beta-xylanase) for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, ducks for fattening/laying, turkeys for laying, quails, pheasants, partridges, guinea fowl, geese for fattening/laying, pigeons, ostriches, peacocks, flamingos and ornamental birds. (EFSA-Q-2010-01295)

Not discussed due to lack of time.

5.4. Kemzyme Plus Dry (endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, alpha-amylase, bacillolysin and endo-1,4-beta-xylanase) for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, ducks for fattening/laying, turkeys for laying, quails, pheasants, partridges, guinea fowl, geese for fattening/laying, pigeons, ostriches, peacocks, flamingos, ornamental birds, piglets (weaned) (EFSA-Q-2010-01297)

Not discussed due to lack of time.

⁷ <http://www.efsa.europa.eu/en/events/event/150428-m.pdf>

⁸ During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.

5.5. L-tryptophan for all animal species (EFSA-Q-2011-00946)

Not discussed due to lack of time.

5.6. Lysine (Concentrated liquid L-lysine (base), L-lysine monohydrochloride, technically pure, L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum*) for all animal species (EFSA-Q-2011-00991)

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of different forms of L-lysine produced by several strains of *Corynebacterium glutamicum* as nutritional additives for all animal species.

The draft opinion was discussed. However, due to lack of time it was not possible to finalise the discussion and it was agreed to send the opinion to the next available plenary.

5.7. L-lysine (L-lysine monohydrochloride and L-lysine sulphate) for all animal species (EFSA-Q-2011-00996)

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of L-lysine monohydrochloride produced by *Escherichia coli* (CGMMC 3705) and L-lysine sulphate produced by *Corynebacterium glutamicum* (CGMCC 3704) as nutritional additives for all animal species.

The draft opinion was discussed. The Panel concluded that L-lysine monohydrochloride is safe for the target species, consumers and the environment, but it is hazardous by inhalation for users. It is considered an efficacious source of L-lysine. The same conclusions would apply to L-lysine sulphate. However, due to the poor characterisation of the genetic modification of the production strain and the uncertainties regarding the possible presence of its recombinant DNA including antibiotic resistance genes in the product, the Panel could not conclude on the safety of L-lysine sulphate produced by *Corynebacterium glutamicum* (CGMCC 3704) for target species, consumers, users and environment.

The opinion was adopted.

5.8. L-threonine for all animal species (EFSA-Q-2012-00113)

Not discussed due to lack of time.

5.9. Cylactin[®]/Cernivet[®] (*Enterococcus faecium* NCIMB 10415) for piglets (suckling and weaned), pigs for fattening and sows (EFSA-Q-2012-00419)

A member of the WG presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Cylactin[®]/Cernivet[®] (*Enterococcus faecium* NCIMB 10415) as a zootechnical additive for pigs.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species and efficacious in sows/suckling piglets and weaned piglets. However, efficacy was not demonstrated in pigs for fattening.

The opinion was adopted.

5.10. Enzy Phostar (6-phytase) for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, laying hens, minor avian species including laying birds (game birds, geese, pigeons, sporting and ornamental birds), weaned piglets, pigs for fattening, sows for reproduction and minor porcine species (EFSA-Q-2013-0022)

The Chair of the WG presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Enzy Phostar (6-phytase) as a zootechnical additive for avian species and pigs.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumers and the environment, while some concerns were expressed with regards the safety for the user. The Panel also concluded that the additive is efficacious when used in the target species under application.

The opinion was adopted.

5.11. L-Lysine sulphate produced by fermentation with *Escherichia coli* for all animal species (EFSA-Q-2014-00003)

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-lysine sulphate produced by *Escherichia coli* (CGMC 3705) when used as nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumers and the environment, but it should be considered a hazard by inhalation. The Panel also concluded that the additive is an efficacious source of L-lysine for all animal species.

The opinion was adopted.

5.12. VevoVitall® (benzoic acid) for pigs for reproduction (gestating and lactating sows, gilts and boars) (EFSA-Q-2014-00551)

The rapporteur presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety and efficacy of VevoVitall® (benzoic acid) as a zootechnical additive for pigs for reproduction, based on additional data provided by the applicant.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species and that it has the potential to introduce a small reduction of urine pH in sows. However, an effect on urinary pH alone is of little relevance, unless shown to be linked to a clear beneficial effect on animal production, performance, welfare or on the environmental consequences of animal production. No conclusion on efficacy could be drawn for boars and gilts.

The opinion was adopted.

6. New mandates

6.1. New applications under Regulation (EC) No 1831/2003

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, who accepted it:

EFSA-Q-Number	Subject
EFSA-Q-2015-00280	<i>Lactobacillus brevis</i> TAK 124-1 NCIMB 42149 (AerobEst) for all animal species
EFSA-Q-2015-00278	<i>Lactobacillus plantarum</i> TAK 59 NCIMB 42150 for all animal species
EFSA-Q-2015-00287	Levucell SB 20/SB 10 ME/Levucell SB Titan (<i>Saccharomyces cerevisiae boulardii</i> CNCM I-1079) for chickens for fattening
EFSA-Q-2015-00296	Calsporin® (<i>Bacillus subtilis</i> C-3102 DSM 15544) for sows and suckling piglets
EFSA-Q-2015-00346	B-Act (<i>Bacillus licheniformis</i> DSM 28710) for chickens for fattening, chickens reared for laying

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-2015-00164	<i>Bacillus subtilis</i> DSM 28343 for chickens for fattening	24/04/2015
EFSA-Q-2015-00033	Monteban™ G100 (Granular narasin, equivalent to 100g narasin activity) for ducks	28/04/2015
EFSA-Q-2014-00832	Probion Forte (Preparation of <i>Bacillus subtilis</i> and <i>Bacillus coagulans</i>) for chickens for fattening, chickens reared for laying, laying hens	30/04/2015
EFSA-Q-2014-00729	<i>Bacillus subtilis</i> DSM27273 for piglets (weaned), weaned minor porcine species	30/04/2015
EFSA-Q-2014-00889	E462 Ethyl Cellulose for all animal species	12/05/2015
EFSA-Q-2015-00032	Maxiban G160 (Narasin 80 g activity/kg and Nicarbazine 80 g/kg) for chickens for fattening	12/05/2015
EFSA-Q-2014-00887	E 551a Silicic acid, precipitated and dried and E 551b colloidal silica for all animal species	18/05/2015
EFSA-Q-2015-00179	Enviva® PRO 202 GT (<i>Bacillus amyloliquefaciens</i> BS 15A-P4, <i>Bacillus amyloliquefaciens</i> LSSA01, <i>Bacillus amyloliquefaciens</i> BS2084) for chickens for fattening, chickens reared for laying, minor poultry species for fattening and to point of lay, except laying birds	18/05/2015
EFSA-Q-2014-00636	Betaine Anhydrous for all animal species	22/05/2015
EFSA-Q-2014-00213	Dry grape extract for all animal species	22/05/2015
EFSA-Q-2015-00167	Coxidin (monensin sodium) for chickens for fattening, chickens reared for laying	28/05/2015

EFSA-Q-2015-00239	Calsporin® (<i>Bacillus subtilis</i> C-3102 DSM 15544) for Koi carp and ornamental fish	28/05/2015
EFSA-Q-2014-00890	Natrolith-Phonolith for all animal species	04/06/2015

These applications were assigned to the respective working groups.

6.3. New applications under Regulation (EC) No 178/2002

EFSA-Q-Number	Subject
EFSA-Q-2015-00314	SUILECTIN™ (<i>Phaseolus vulgaris</i> lectins)
EFSA-Q-2015-00252	L-threonine, technically pure for all animal species
EFSA-Q-2015-00251	L-tryptophan, technically pure for all animal species
EFSA-Q-2015-00286	Allura red AC for cats and dogs
EFSA-Q-2015-00295	Friedland Clay (montmorillonite-illite mixed layer clay) for all animal species
EFSA-Q-2015-00367	Inositol for cats and dogs

7. Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA, the European Commission

7.1. Scientific Committee and other Scientific Panels

- The Chair of the Panel provided some feedback on the items discussed during the last plenary of the Scientific Committee.
- A member of the Panel provided feedback on the Scientific Committee's WG on insects.

7.2. Working groups

- Not discussed.

7.3. EFSA

- The Panel was informed about the outcome of the info session on feed additives applications that took place on 5-6 May in Barcelona.

8. Other scientific topics for information and/or discussion

Not discussed

9. Any Other Business

The Head of the REPRO Department thanked the Panel experts for their commitment to EFSA and the work done.

The Chairman closed the last Plenary meeting of the current Panel's mandate thanking all the experts for their work and dedication during the last three years.