

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

Minutes of the 111th plenary meeting

Held on 28-30 April 2015, Parma

(Agreed on 16 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, Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Fernando Ramos, Derek Renshaw, Guido Rychen,¹ Maria Saarela, Kristen Sejrsen, Patrick van Beelen, John Wallace and Johannes Westendorf.²

- **Hearing Experts:**³

- N/A

- **European Commission and/or Member States representatives:**

- N/A

- **EFSA:**

- **FEED Unit:** Manuela Tiramani, Jaume Galobart, Jaime Aguilera, Rosella Brozzi, Matteo Innocenti, Gloria López-Gálvez, Paola Manini, Oriol Ribó, Jordi Tarrés-Call and Maria Vittoria Vettori.

- **Observers**

- N/A

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted after removal of the items "L-Threonine for all animal species (EFSA-Q-2012-00113)", "Ferric oxide for all animal species (EFSA-Q-2012-00492)" and "Lactic acid and calcium lactate for all animal species (EFSA-Q-2010-01221)".

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest,⁵ EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the experts invited for the present meeting. No conflicts of interests related to the

¹ Present only on 28 and 29 April.

² Present only on 28 and 29 April.

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

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

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 110th Plenary meeting held on 10-12 March 2015

The minutes of the 110th Plenary meeting were reviewed and agreed.⁶

5. Scientific outputs submitted for discussion and possible adoption⁷

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

Not discussed due to lack of time.

5.2. Indigo carmine for cats, dogs and ornamental fish (EFSA-Q-2010-01533)

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 indigo carmine as a sensory additive for cats, dogs and ornamental fish.

The draft opinion was discussed. The Panel concluded that indigo carmine (colouring purity of at least 93 %) is safe for cats and dogs at a level of 250 mg/kg complete feed and for ornamental fish at 1 000 mg/kg complete feed. The additive should be considered as a skin and respiratory sensitisier and hazardous by inhalation. The Panel also concluded that indigo carmine is effective in adding colour to feedingstuffs.

The opinion was adopted.⁸

5.3. Lysine (Concentrated liquid L-lysine (base), L-lysine monohydrochloride, technically pure, L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* (solid form and liquid form)) 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. The Panel requested the working group to prepare an updated draft based on the discussion.

5.4. Vitamin B₁₂ (cyanocobalamin) for all animal species (EFSA-Q-2012-00455)

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 vitamin B₁₂ as a 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. It should be considered irritant to skin and eyes, a skin sensitisier and hazardous by

⁶ <http://www.efsa.europa.eu/en/events/event/150310c-m.pdf>

⁷ During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.

⁸ <http://www.efsa.europa.eu/en/efsajournal/pub/4108.htm>

inhalation. The Panel also concluded that the additive is effective in meeting the animal's requirement for vitamin B₁₂.

The opinion was adopted.⁹

5.5. Ferrous carbonate for all animal species (EFSA-Q-2012-00495)

The Chair of the working group (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 ferrous carbonate as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that ferrous carbonate is safe when supplied up to the maximum iron content per kilogram complete feedingstuff of 450 mg for bovines and poultry, 500 mg for ovines, 600 mg for pets and 750 mg for other species/categories, except horses and fish; for piglets up to one week before weaning a daily maximum dose of 250 mg Fe is considered safe. Because of insufficient data, the Panel is not in a position to derive a maximum safe iron concentration in feed for horses or fish; as a provisional measure, the current value for other animal species (750 mg/kg) could be maintained. The additive is safe for consumers and the environment but it is a hazard for users. The Panel also concluded that ferrous carbonate may be sufficiently efficacious in adult animals, but it would be insufficiently bioavailable for young animals. The Panel recommended a reduction of the currently authorised maximum iron content in complete feed for bovines, poultry and pets.

The opinion was adopted.¹⁰

5.6. Complexation products of sodium tartrates with iron(III) chloride for all animal species (EFSA-Q-2012-00947)

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 complexation products of sodium tartrates with iron(III) chloride as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target animals, consumers, users and the environment. The Panel also concluded that the additive has the potential to be efficacious as an anticaking agent in salt.

The opinion was adopted.¹¹

5.7. AGal-Pro BL and AGal-Pro BL-L (alpha-galactosidase and endo-1,4-beta-glucanase) for laying hens and minor laying birds (EFSA-Q-2013-00582)

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 AGal-Pro (alpha-galactosidase and endo-1,4-beta-glucanase) as a zootechnical additive for laying hens and minor laying birds.

The draft opinion was discussed. The Panel concluded that the additive is safe and efficacious for the target species under assessment.

The opinion was adopted.¹²

⁹ <http://www.efsa.europa.eu/en/efsajournal/pub/4112.htm>

¹⁰ <http://www.efsa.europa.eu/en/efsajournal/pub/4109.htm>

¹¹ <http://www.efsa.europa.eu/en/efsajournal/pub/4114.htm>

5.8. Formic acid, ammonium formate and sodium formate for all animal species (EFSA-Q-2013-00755)

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of formic acid, ammonium formate and sodium formate as technological additives for all animal species.

The draft opinion was discussed. The Panel concluded that formic acid and sodium formate are safe for the target species, while concerns arise from ammonium formate due to the presence of formamide. The additives are considered safe for the consumer with the exception of ammonium formate for which concerns were expressed for the potential exposure of consumers of eggs and milk to formamide. The additives are considered safe for the environment but are hazardous for users. The Panel also concluded that although formic acid could be effective, limited data are available for ammonium formate and sodium formate.

The opinion was adopted.¹³

5.9. L-valine (minimum: 98% L-valine) for all animal species (EFSA-Q-2014-00299)

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-valine as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target animals, consumers, users and the environment and is considered an efficacious source of L-valine.

The opinion was adopted.¹⁴

5.10. Rovabio® Spiky (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for turkeys and minor poultry species for fattening, reared for laying or breeding (EFSA-Q-2014-00463)

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 Rovabio® Spiky (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) as a zootechnical additive for turkeys and minor poultry species for fattening, reared for laying or breeding.

The draft opinion was discussed. The Panel concluded that the additive is safe and efficacious for the target species under assessment.

The opinion was adopted.¹⁵

5.11. Fecinor® (*Enterococcus faecium* CECT 4515) for piglets (weaned) (EFSA-Q-2015-00055)

The rapporteur presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the efficacy of Fecinor® (*Enterococcus faecium* CECT 4515) as a zootechnical additive for weaned piglets, based on additional data provided by the applicant.

¹² <http://www.efsa.europa.eu/en/efsjournal/pub/4107.htm>

¹³ <http://www.efsa.europa.eu/en/efsjournal/pub/4113.htm>

¹⁴ <http://www.efsa.europa.eu/en/efsjournal/pub/4110.htm>

¹⁵ <http://www.efsa.europa.eu/en/efsjournal/pub/4106.htm>

The draft opinion was discussed. The Panel concluded that the additive has the potential to be efficacious in weaned piglets.

The opinion was adopted.¹⁶

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-2015-00164	<i>Bacillus subtilis</i> DSM 28343 for chickens for fattening
EFSA-Q-2015-00167	Coxidin (monensin sodium) for chickens for fattening, chickens reared for laying
EFSA-Q-2015-00188	Zinc chelate of methionine (Zn-Met) (Zinpro 180) for all animal species
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 all animal species
EFSA-Q-2015-00239	Calsporin® (<i>Bacillus subtilis</i> C-3102 - DSM 15544) for Koi carp and ornamental fish

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-2014-00634	Natural Mixtures of talc (steatite) and chlorite (E 560) for all animal species	09/03/2015
EFSA-Q-2014-00909	Cumin tincture for all animal species	13/03/2015
EFSA-Q-2015-00054	Natuphos® E 5000; Natuphos® E 5000 L; Natuphos® E 10000 L; Natuphos® E 25000 L (6-phytase) for all pigs, all avian species	27/03/2015
EFSA-Q-2015-00145	BIOMIN® BBSH 797 - DSM 11798; Genus nov. species nov. (BIOMIN® BBSH 797) for all avian species	13/04/2015
EFSA-Q-2014-00666	MAXIBAN® G160 (Narasin 80 g activity/kg and Nicarbazin 80 g/kg)	14/04/2015
EFSA-Q-2014-00229	Feedlyve AGL (endo-1,4(3)-beta-glucanase) for chickens for fattening	16/04/2015
EFSA-Q-2014-00228	Feedlyve AXC (endo-1,4-beta-xylanase) for chickens for fattening	16/04/2015
EFSA-Q-2014-00115	Hemicell® HT, Hemicell® HT-L (endo-1,4-beta-mannanase) for piglets (weaned), pigs for fattening, minor porcine species, chickens for fattening, chickens reared for laying, minor poultry species, turkeys	17/04/2015

¹⁶ <http://www.efsa.europa.eu/en/efsajournal/pub/4111.htm>

	reared for breeding, turkeys for fattening	
EFSA-Q-2015-00053	Preparation of algae interspaced bentonite for all animal species	21/04/2015

These applications were assigned to the respective working groups.

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 biological relevance.

7.2. Working groups

- The Working Group on Coccidiostats requested the advice of the Panel on the acceptability of some studies submitted for the assessment of safety for target species and efficacy for a synthetic coccidiostat.

7.3. EFSA

- The Panel was informed about the upcoming info session on feed additives applications that will take place on 5-6 May in Barcelona.

8. Other scientific topics for information and/or discussion

Not discussed

9. Any Other Business

Not discussed