

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

Minutes of the 125th Plenary meeting

Held on 21-23 March 2017, Parma (Italy)

(Agreed by written procedure on 31 March 2017)

Participants

■ Panel Members

Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli,¹ Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Marta López Alonso, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

■ Hearing Experts:

Andy Hart²

■ European Commission and/or Member States representatives:

Marta Ponghellini (DG SANTE)

■ EFSA:

FEED Unit: Jaime Aguilera, Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini, Manuela Tiramani and Maria Vittoria Vettori.

AMU Unit: Elisa Aiassa³, Laura Martino⁴

DATA Unit: Davide Arcella,⁵ Bruno Dujardin⁵ and Rita Sousa⁵

SCER Unit: Caroline Mertens⁶

¹ Present on 21 and 23 March

² Present on 22 March for item 7.3.b.

³ Present on 22 March for item 7.3.b.

⁴ Present on 21 March for item 5.11.

⁵ Present on 23 March for item 5.13.

⁶ Present on 22 March for item 7.3.b.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Secundino López Puente.

2. Adoption of agenda

The agenda was adopted with the deletion of the item "Avatec[®] 150G (Lasalocid A sodium) for chickens for fattening, chickens reared for laying, turkeys for fattening, minor avian species (pheasants, guinea fowl, quails and partridges), except laying birds (EFSA-Q-2013-00813).

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Panel Members invited for the present meeting. No Conflicts of Interest 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 124th Plenary meeting held on 24-26 January 2017

The minutes of the 124th Plenary meeting held on 24-26 January 2017 were agreed by written procedure on 2 February 2017.⁹

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

5.1 Annatto F (norbixin potassium) for cats and dogs ([EFSA-Q-2010-01521](#))

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 Annatto F (norbixin potassium) as a sensory additive for cats and dogs.

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁹ <http://www.efsa.europa.eu/sites/default/files/event/170124-0m.pdf>

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, the safety for the target species and user and the efficacy. The opinion was adopted.

5.2 Amylofeed (endo-1,3(4)-beta-glucanase, endo-1,4-beta-xylanase and alpha-amylase) for piglets and minor porcine species ([EFSA-Q-2014-00503](#))

Not discussed due to lack of time.

5.3 Probion Forte (*Bacillus subtilis* KCCM 10941P and *Bacillus coagulans* KCCM 11093P) for chickens for fattening, chickens reared for laying and laying hens ([EFSA-Q-2014-00832](#))

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 Probion Forte (*Bacillus subtilis* KCCM 10941P and *Bacillus coagulans* KCCM 11093P) as a zootechnical additive for chickens for fattening, chickens reared for laying and laying hens.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, the safety for the target species, consumer, user and environment and the efficacy. The opinion was adopted.

5.4 Calsporin[®] (*Bacillus subtilis* DSM 15544) for dogs ([EFSA-Q-2015-00004](#))

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 Calsporin[®] (*Bacillus subtilis* DSM 15544) as a zootechnical additive for dogs.

The draft opinion was discussed. Discussion focussed mainly on the efficacy. The opinion was adopted.

5.5 Calsporin[®] (*Bacillus subtilis* DSM 15544) for sows and suckling piglets ([EFSA-Q-2015-00296](#))

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 Calsporin[®] (*Bacillus subtilis* DSM 15544) as a zootechnical additive for sows and suckling piglets.

The draft opinion was discussed. Discussion focussed mainly on the efficacy. The opinion was adopted.

5.6 *Lactobacillus acidophilus* D2/CSL (*Lactobacillus acidophilus* CECT 4529) for chickens for fattening ([EFSA-Q-2015-00429](#))

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 *Lactobacillus acidophilus* D2/CSL as a zootechnical additive for chickens for fattening.

The draft opinion was discussed. Discussion focussed mainly on the efficacy. The opinion was adopted.

5.7 Zinc chelate of methionine hydrate (BIOMET[®] Zn) for all animal species ([EFSA-Q-2015-00549](#))

Not discussed due to lack of time.

5.8 L-Threonine for produced by *Escherichia coli* for all animal species ([EFSA-Q-2016-00074](#))

Not discussed due to lack of time.

5.9 Optiphos[®] (6-phytase) for all finfish ([EFSA-Q-2016-00291](#))

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 Optiphos[®] (6-phytase) as a zootechnical additive for all finfish.

The draft opinion was discussed. Discussion focussed mainly on the safety for target species and the efficacy. The opinion was adopted.

5.10 L-Arginine produced by fermentation with *Corynebacterium glutamicum* KCCM80099 (L-arginine feed grade) for all animal species ([EFSA-Q-2016-00405](#))

Not discussed due to lack of time.

5.11 Guidance on the assessment of the safety of feed additives for the target species ([EFSA-Q-2016-00553](#))

The Chair of the WG presented the question and the draft guidance. This question refers to the self-task of the Panel on the revision of the guidance documents.

The draft guidance was discussed. This guidance documents covers the assessment of the safety of feed additives for the target species. The draft guidance was endorsed for public consultation.

5.12 *Lactobacillus hilgardii* CNCM I-4785 for all animal species ([EFSA-Q-2016-00580](#))

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 *Lactobacillus hilgardii* CNCM I-4785 as a technological additive for all animal species.

The draft opinion was discussed in detail in the previous plenary. The opinion was adopted.

5.13 Guidance on the assessment of the safety of feed additives for the consumer ([EFSA-Q-2016-00822](#))

The Chair of the WG presented the question and the draft guidance. This question refers to the self-task of the Panel on the revision of the guidance documents.

The draft guidance was discussed. The new consumer exposure model based on the EFSA comprehensive European food consumption database was presented and discussed. The draft will be further discussed in the next plenary.

5.14 Guidance on the identity, characterisation and conditions of use of feed additives ([EFSA-Q-2016-00823](#))

Not discussed due to lack of time.

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-2017-00051	Probiotic Lactina® (<i>Enterococcus faecium</i> NBIMCC 8270, <i>Lactobacillus acidophilus</i> NBIMCC 8242, <i>Lactobacillus helveticus</i> NBIMCC 8269, <i>Lactobacillus delbrueckii</i> ssp. <i>lactis</i> NBIMCC 8250, <i>Lactobacillus delbrueckii</i> ssp. <i>bulgaricus</i> NBIMCC 8244 and <i>Streptococcus thermophilus</i> NBIMCC 8253) for chickens for fattening, rabbits (suckling and weaned)
EFSA-Q-2017-00103	Benzoic acid for pigs for fattening
EFSA-Q-2017-00127	Hostazym® (endo-1,4-beta-xylanase) for carp

EFSA-Q-2017-00049	<i>Lactobacillus reuteri</i> NBF 1 (<i>Lactobacillus reuteri</i> DSM 32203) for dogs
EFSA-Q-2017-00090	<i>Bacillus subtilis</i> DSM 28343 for turkeys for calves for rearing
EFSA-Q-2017-00050	<i>Lactobacillus reuteri</i> NBF 2 (<i>Lactobacillus reuteri</i> DSM 32264) for cats

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-2016-00669	<i>Lactobacillus buchneri</i> NRRL B-50733 for all animal species	24/01/2017
EFSA-Q-2016-00783	L-Arginine for pigs for all animal species	25/01/2017
EFSA-Q-2016-00818	Taminizer D (dimethylglycine sodium salt) for chickens for fattening	28/02/2017
EFSA-Q-2016-00842	Ronozyme® WX (CT)/Ronozyme® WX (L) (endo-1,4-beta-xylanase) for laying hens	31/01/2017
EFSA-Q-2017-00025	Natugrain® Wheat TS (endo-1,4-beta-xylanase) for turkeys for fattening, chickens for fattening and ducks, turkeys reared for breeding, ornamental birds, minor avian species except ducks and laying birds	10/03/2017
EFSA-Q-2017-00073	Fumonisin esterase (FUMzyme®) for pigs and all avian species	02/03/2017
EFSA-Q-2016-00858	Benzoic acid for suckling piglets, weaned piglets, pigs for fattening, sows for reproduction, sows in order to have benefit in piglets, minor porcine species, chickens for fattening, chickens reared for laying, laying hens, breeding hens, turkeys for fattening, turkeys for breeding purposes, turkeys reared for breeding, minor poultry species	07/02/2017
EFSA-Q-2016-00861	VevoVital® (Benzoic acid) for minor porcine species	08/02/2017

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-2016-00859	Omega-6-fatty acid as octadecadienoic acid (conjugated linoleic acid-methylester) (Lutalin) for pigs for fattening, sows and cows
EFSA-Q-2017-00047	AviMatrix® (benzoic acid, calcium formate and fumaric acid) for chickens for fattening, chickens reared for laying, minor avian species for fattening and to point of lay
EFSA-Q-2017-00080	Hexamethylene tetramine for pigs, poultry, bovines, sheep, goats, rabbits and horses

These questions were assigned to the respective working groups.

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

7.1 EFSA

Not discussed.

7.2 Scientific Committee

- a) A member of the WG on genotoxicity of the Scientific Committee informed the Panel of the new mandate from the European Commission for clarification and consideration of several aspects to assessment of genotoxicity ([EFSA-Q-2017-00074](#)).

7.3 Working Groups

- a) The Chairs of the WGs involved in the update of the guidance documents provided an overview of the current state of the update of the different guidance documents.
- b) The Chair of the WG on amino acids and vitamins presented the report of the FEEDAP case study for testing the application of the draft guidance on uncertainty and the principles of the PROMETHEUS (PROMoting METHods for Evidence Use in Scientific assessments) project. The pilot was conducted by applying *a priori* developed protocols on the assessment of the safety for target animals, safety for the consumer and efficacy to a zootechnical feed additive. The Panel provided its views on the potential benefits (overall it was agreed that the principles behind PROMETHEUS may support the consistency of the assessments) and also its reservations about the default application of this procedure, mainly in the area of the assessment of efficacy. The pilot cases performed across EFSA will be discussed in broader WG and Workshop meetings.

8. Other scientific topics for information and/or discussion

- a) The WG on Technological additives presented a question to the Panel regarding the assessment of safety for the target animals of a clay. The question related to the acceptability of the design of the tolerance studies presented in the dossier.

9. Any other business

- a) The Panel was informed that the July plenary (4-6 July) will be held in Lisbon.