

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

Minutes of the 133rd Plenary meeting

Held on 12-14 June 2018, Parma (Italy)

(Agreed by written procedure on 19 June 2018)

Participants

■ **Panel Members**

Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Marta López-Alonso, Secundino López Puente¹, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

■ **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, Chiara Mula, Jordi Tarrés-Call, Manuela Tiramani and Maria Vittoria Vettori.

LAS Unit: Simone Gabbi²

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

¹ Participated via webconference

² Participated on 13 June for item 7.1

2. Adoption of agenda

The agenda was adopted after the deletion of the items “Botanically defined flavourings from Botanical Group 09 - Zingiberales for all animal species and categories: cardamom oil from *Elettaria cardamomum* (L.) Maton (EFSA-Q-2010-01293)” and “*Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323 for all animal species (EFSA-Q-2018-00287)”

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, 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.

For further details on the outcome of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

4. Report on the written procedures since 132nd Plenary meeting

The minutes of the 132nd Plenary meeting held on 17-19 April 2018 were agreed by written procedure on 26 April 2018.⁵

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

5.1. Vitamin B12 (cyanocobalamin) for all animal species (EFSA-Q-2012-00456)

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 Vitamin B12 (cyanocobalamin) as a nutritional additive for all animal species.

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

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁵ http://www.efsa.europa.eu/sites/default/files/event/feedap180417_m.pdf

5.2. Monimax (monensin sodium and nicarbazin) for chickens for fattening, chickens reared for laying ([EFSA-Q-2012-00791](#))

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 Monimax (monensin sodium and nicarbazin) as a coccidiostat for chickens for fattening and chickens reared for laying.

The draft opinion was discussed, focusing mainly on the safety for the target species and efficacy of the additive. The draft opinion will be amended according to the discussions and will be presented for adoption in a future plenary meeting.

5.3. Vitamin B2 (riboflavin) for all animal species ([EFSA-Q-2012-00953](#))

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 Vitamin B2 (riboflavin) as a nutritional additive for all animal species.

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

5.4. Aviax 5% (semduramicin sodium) for chickens for fattening ([EFSA-Q-2014-00219](#) and [EFSA-Q-2015-00714](#))

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of Aviax 5% (semduramicin sodium) as a coccidiostat for chickens for fattening.

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

5.5. Betaine anhydrous for all animal species ([EFSA-Q-2014-00636](#))

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 Betaine anhydrous as a nutritional additive for all animal species.

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

5.6. Sodium molybdate dihydrate for sheep ([EFSA-Q-2015-00766](#))

Not discussed due to lack of time.

5.7. Calsporin® (*Bacillus subtilis* C-3102 (DSM 15544)) for chickens for fattening ([EFSA-Q-2016-00089](#))

The rapporteur presented the question and the draft opinion. This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Calsporin® (*Bacillus subtilis* C-3102 (DSM 15544)) as a zootechnical additive for chickens for fattening.

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

5.8. Actisaf® Sc47 (*Saccharomyces cerevisiae*) for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, horses and pigs for fattening ([EFSA-Q-2016-00090](#), [EFSA-Q-2016-00297](#), [EFSA-Q-2016-00292](#) and [EFSA-Q-2017-00286](#))

The rapporteur presented the questions and the draft opinion. These questions refer to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Actisaf® Sc47 (*Saccharomyces cerevisiae*) as zootechnical additive for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, horses and pigs for fattening.

The draft opinion was discussed. Discussion focussed mainly on the characterisation and on the safety for the target species, consumer and user. The Panel unanimously adopted the opinion.

5.9. Coxam (amprolium) for chickens for fattening and chickens reared for laying ([EFSA-Q-2016-00290](#))

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 (1) of Regulation (EC) No 1831/2003 of Coxam (amprolium) as a coccidiostat for chickens for fattening and chickens reared for laying.

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

5.10. Muramidase produced by *Trichoderma reesei* (DSM 32338) for chickens for fattening and minor poultry species ([EFSA-Q-2017-00632](#))

The Chair of the working group (WG) presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Muramidase produced by *Trichoderma reesei* (DSM 32338) as a zootechnical additive for chickens for fattening and minor poultry species.

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

5.11. 1c322i - lecithins liquid, 1c322ii - hydrolysed lecithins, 1c322iii - lecithins de-oiled ([EFSA-Q-2018-00309](#))

EFSA presented the question and the draft opinion. This question refers to the modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of lecithins liquid, hydrolysed lecithins, lecithins de-oiled as technological additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive. 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-2018-00439	<i>Arctium lappa</i> extract (Great Burdock extract CoE 57) for cats and dogs
EFSA-Q-2018-00320	<i>Panax ginseng</i> C. A. Mey. (Ginseng extract CoE 318) for cats and dogs
EFSA-Q-2018-00440	<i>Garcinia cambogia</i> Desr. (Garcinia extract) for cats and dogs
EFSA-Q-2018-00441	<i>Plantago ovata</i> L. husk (Fleawort absolute) for cats and dogs
EFSA-Q-2018-00318	<i>Ginkgo biloba</i> L. extract for cats and dogs
EFSA-Q-2018-00319	<i>Echinachea angustifolia</i> DC. extract (Blacksamson echinacea extract) and <i>Echinachea purpurea</i> (L.) Moench. extract (Echinacea extract) for cats and dogs

EFSA-Q-2018-00438	L-Histidine monohydrochloride monohydrate (feed grade) produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM80172 for all animal species
EFSA-Q-2018-00309	1c322i - lecithins liquid, 1c322ii - hydrolysed lecithins, 1c322iii - lecithins de-oiled for all animal species
EFSA-Q-2018-00427	L-lysine formulated as L-lysine monohydrochloride and L-lysine sulphate for all animal species
EFSA-Q-2018-00428	Carvacrol for salmon and trout
EFSA-Q-2018-00417	Endo-1,4-beta-xylanase and endo-1,4-beta-glucanase for piglets (weaned), laying hens, chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, turkeys for breeding purposes, ducks for fattening, all minor avian species for laying, minor poultry species for fattening (other than ducks for fattening) and ornamental birds
EFSA-Q-2018-00418	Preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol for chickens for fattening, chickens reared for laying and minor avian species other than laying species
EFSA-Q-2018-00419	<i>Enterococcus faecium</i> DSM 7134 for laying hens
EFSA-Q-2018-00420	Endo-1,4-beta-xylanase for rabbits for fattening
EFSA-Q-2018-00421	6-phytase for piglets (weaned), pigs for fattening, sows for reproduction, minor porcine species, chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, minor avian species excluding laying birds, minor avian species for laying
EFSA-Q-2018-00422	<i>Lactobacillus rhamnosus</i> and <i>Lactobacillus farciminis</i> for piglets (weaned)
EFSA-Q-2018-00442	L-Lysine monohydrochloride and concentrated liquid Lysine, produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM10227 for all animal species
EFSA-Q-2018-00451	L-Tryptophan produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM80176 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-2018-00320	<i>Panax ginseng</i> C. A. Mey. (Ginseng extract CoE 318) for cats and dogs	22/05/2018
EFSA-Q-2018-00318	<i>Ginkgo biloba</i> L. extract for cats and dogs	22/05/2018
EFSA-Q-2018-00319	<i>Echinacea angustifolia</i> DC. extract (Blacksamson echinacea extract) and <i>Echinacea purpurea</i> (L.) Moench. extract (Echinacea extract) for cats and dogs	22/05/2018
EFSA-Q-2017-00743	Tocopheryl phosphate mixture for all animal species	04/04/2018
EFSA-Q-2017-00754	<i>Lactobacillus rhamnosus</i> CNCM I-3698 and <i>Lactobacillus farciminis</i> CNCM I-3699 for all animal species	22/05/2018

EFSA-Q-2017-00756	<i>Lactobacillus rhamnosus</i> CNCM I-3698 and <i>Lactobacillus farciminis</i> CNCM I-3699 for chickens for fattening	22/05/2018
EFSA-Q-2017-00837	Endo-1,4-beta-xylanase and alpha-galactosidase for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying	15/05/2018
EFSA-Q-2018-00060	<i>Bacillus amyloliquefaciens</i> CECT 5940 for chickens for fattening and reared for laying	25/05/2018
EFSA-Q-2018-00083	<i>Saccharomyces cerevisiae</i> CNCM I-1077 for lambs and horses	28/05/2018
EFSA-Q-2018-00084	L-Threonine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM80118 for all animal species	20/04/2018
EFSA-Q-2018-00253	Endo-1,4-beta-xylanase produced by <i>Bacillus subtilis</i> (LMG S-15136) for sows in order to have benefit in piglets and all porcine species and life stages	03/05/2018
EFSA-Q-2018-00254	Manganese chelates of lysine and glutamic acid for all animal species	03/05/2018
EFSA-Q-2018-00255	Iron chelates of lysine and glutamic acid for all animal species	04/05/2018
EFSA-Q-2018-00276	Benzoic acid for piglets (weaned)	30/04/2018
EFSA-Q-2018-00266	L-lysine monohydrochloride and concentrated liquid L-lysine (base) for all animal species	08/05/2018
EFSA-Q-2018-00287	<i>Lactobacillus hilgardii</i> CNCM I-4785 and <i>Lactobacillus buchneri</i> CNCM I-4323 for all animal species	22/05/2018
EFSA-Q-2018-00309	1c322i - lecithins liquid, 1c322ii - hydrolysed lecithins, 1c322iii - lecithins de-oiled for all animal species	28/05/2018

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-2018-00430	Na ₂ EDTA CAS 6381-92-6, Origanum oil CAS 8007-11-2, Thyme oil CAS 8007-46-3, <i>Castanea sativa</i> mill for pigs for fattening
EFSA-Q-2018-00429	Preparation of algae interspaced bentonite for all animal species
EFSA-Q-2018-00339	Natural mixture of illite, montmorillonite and kaolinite for all animal species
EFSA-Q-2018-00341	Ammonium formate for all animal species
EFSA-Q-2018-00372	Ethoxyquin (6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline) for all animal species

These questions were assigned to the respective working groups.

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

7.1. EFSA

A member of the Legal and Assurance Services Unit made a presentation regarding data protection in the context of the authorisation of feed additives under Regulation (EC) No 1831/2003.

7.2. Scientific Committee

Not discussed.

7.3. Working Groups

Not discussed.

8. Other scientific topics for information and/or discussion

8.1. Update on the Guidance on the assessment of safety of feed additives for the environment ([EFSA-Q-2016-00400](#))

EFSA provided an overview of the status of the update of the draft guidance for the assessment of the safety of feed additives for the environment. It is expected that the draft guidance will be discussed in one of the next plenary meetings for endorsement. A public consultation will follow.

9. Any other business

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

Annex

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

With regard to this meeting, Prof. Jürgen Gropp declared the following interest: the dossiers in support of the application on Aviax® (semduramicin sodium) for chickens for fattening (EFSA-Q-2014-00219 and EFSA-Q-2015-00714) contain a published paper (2007) and a study report (2003) in which Prof. Gropp is a co-author. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest,⁷ the experts 'are not allowed to assess, rate or review their own work.' This results in the exclusion of the expert from the discussion and evaluation of the above-mentioned studies.

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

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>