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

Minutes of the 116th Plenary meeting

Held on 1-4 December 2015, Parma (Italy)

(Agreed on 26 January 2016)

Participants

- **Panel Members:**

  Gabriele Aquilina, Vasileios Bampidis, Maria de Lourdes Bastos[1], Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli[2], Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Secundino López Puente, Alberto Mantovani[3], Baltasar Mayo, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

- **Hearing Experts:**

  Not applicable

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

  Not applicable

- **EFSA:**

  FEED Unit: Manuela Tiramani, Jaume Galobart, Jaime Aguilera, Montserrat Anguita, Lucilla Gregoretti, Matteo Lorenzo Innocenti, Paola Manini, Oriol Ribó, Jordi Tarrés-Call and Maria Vittoria Vettori.

  AMU Unit: Laura Martino[4]

  CHAN Unit: Kirsten Haupt[5]

- **Others:**

[1] Present only on 1, 2 and 3 December.
[2] Present only on 1, 2 and 3 December.
[3] Present only on 2, 3 and 4 December.
[4] Present only on 2 December for item 7.1.a.
[5] Present only on 4 December for item 7.1.b.

Not applicable

1. Welcome and apologies for absence

The Chair welcomed all participants. Apologies were received from Marta López-Alonso and Fernando Ramos.

The Chair also welcomed Frida Edman, the new Trainee of the FEED Unit.

2. Adoption of agenda

The agenda was adopted after the deletion of "Chemically defined flavourings from Flavouring Group 28 - Pyridine, pyrrole and quinoline derivatives for all animal species and categories (EFSA-Q-2010-01171)".

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[6] and the Decision of the Executive Director on Declarations of Interest,[7] EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 115th Plenary meeting held on 20-22 October 2015

The minutes of the 115th Plenary meeting were reviewed and agreed.[8]

5. Scientific topics for discussion and/or possible adoption[9,10]

5.1. Chemically defined flavourings from Flavouring Group 14 - Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms for all animal species and categories (EFSA-Q-2010-01218)

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 chemically defined flavourings from Chemical Group 14 as sensory additives for all animal species.

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6 http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
7 http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
8 http://www.efsa.europa.eu/sites/default/files/event/151020a-m.pdf
9 During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.
10 For a detailed outcome of the assessment, please refer to the respective opinions published on the EFSA website.

The draft opinion was discussed. However, due to lack of time the discussion will be continued in the next plenary.

5.2. 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)

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 riboflavin and riboflavin 5'-phosphate ester monosodium salt as nutritional additives for all animal species.

The draft opinion was discussed. The Panel concluded that the additives are safe for the target species, consumer and the environment, while some concerns were expressed for the users. The Panel also concluded that the additives are an effective source of riboflavin.

The opinion was adopted.[11]

5.3. L-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 Chair of the 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 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 concluded that due to several limitations and uncertainties, no conclusions can be drawn on the safety for the target animals, consumers, users and environment for any of the products under assessment, with the exception of concentrated liquid L-lysine (base) produced by *C. glutamicum* NRRL B-50547. For this latter product the Panel concluded that it is safe for the target species, consumer and the environment, but is corrosive. These products are considered as an efficacious source of L-lysine.

The opinion was adopted.

[11] http://www.efsa.europa.eu/en/efsajournal/pub/4349

5.4. Biostrong® 510 (preparation of essential oil of thyme and star anise) for chickens and minor avian species for fattening and rearing up to the point-of-lay (EFSA-Q-2011-01152)

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 Biostrong® 510 (a preparation of essential oil of thyme and star anise) as a zootechnical additive for chickens and minor avian species for fattening and rearing up to the point-of-lay.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumers and the environment but expressed concerns regarding the safety for the user. The Panel also concluded that the additive has the potential to be efficacious.

The opinion was adopted.

5.5. Guanidinoacetic acid for pigs, chickens for fattening and chickens reared for breeding (EFSA-Q-2012-00273)

Not discussed due to lack of time.

5.6. Omega-6-fatty acid as octadecadienoic acid (conjugated linoleic acid-methylester) for pigs for fattening, sows for reproduction, sows (in order to have benefits in piglets), dairy cows for milk production, cows for reproduction (EFSA-Q-2012-00398)

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 conjugated linoleic acid-methylester a nutritional additive for pigs and cows.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species and the environment, and unlikely to raise concerns for consumer safety. Concerns were expressed for user safety. The Panel also concluded that the use of the additive in pigs is effective in reducing subcutaneous fat in the carcass and increasing intramuscular fat and fat firmness. In dairy cows, it reduces milk fat content and has the potential to reduce milk fat yield and milk energy output.

The opinion was adopted.[12]

[12] http://www.efsa.europa.eu/en/efsajournal/pub/4348

5.7. Manganese (manganous chloride tetrahydrate, manganous oxide, manganese sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of glycine hydrate) for all animal species (EFSA-Q-2012-00437)

Not discussed due to lack of time.

5.8. Iron (7 forms) for all animal species (EFSA-Q-2012-00491)

Not discussed due to lack of time

5.9. Natural mixture of illite, montmorillonite and kaolinite (Argile verte du Velay (Velay Green Clay)) for all animal species (EFSA-Q-2013-00069)

A member 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 a natural mixture of illite, montmorillonite and kaolinite as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for cattle for fattening, piglets and pigs for fattening, but could not conclude on the safety for other target species or categories. The Panel also concluded that the additive is safe for the consumers and the environment and is efficacious as anticaking agent and as a binder. The additive should be considered as a dermal sensitiser.

The opinion was adopted.[13]

5.10. Natural mixture of dolomite plus magnesite and magnesium-phyllosilicates (Fluidol) for all animal species (EFSA-Q-2013-00431)

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 a natural mixture of dolomite plus magnesite and magnesium-phyllosilicates as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for dairy cows, piglets and pigs for fattening, but could not conclude on the safety for other target species or categories. The Panel also concluded that the additive is safe for the consumers, users and the environment and is efficacious as anticaking agent.

[13] http://www.efsa.europa.eu/en/efsajournal/pub/4342

The opinion was adopted.[14]

5.11. Natugrain®TS & TS L (endo-1,4-beta-xylanase and endo-1,4-beta-glucanase) for chickens for fattening (EFSA-Q-2014-00291)

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 Natugrain®TS & TS L (endo-1,4-beta-xylanase and endo-1,4-beta-glucanase) as a zootechnical additive for chickens for fattening.

The draft opinion was discussed. The Panel concluded that the additive is a dermal sensitiser but could not conclude on the efficacy.

The opinion was adopted.[15]

5.12. L-Arginine produced by fermentation with *Corynebacterium glutamicum* (KCTC 10423 BP) (EFSA-Q-2014-00296)

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 L-Arginine produced by fermentation with *Corynebacterium glutamicum* (KCTC 10423 BP) 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, the consumers, users and the environment, and is an efficacious source of the amino acid L-arginine.

The opinion was adopted.[16]

5.13. Benzoic acid for pigs for fattening and all animal species (EFSA-Q-2014-00352)

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 benzoic acid as a technological additive for pigs for fattening and as a sensory additive for all animal species .

The draft opinion was discussed. The FEEDAP Panel reiterated its former conclusion that the use of benzoic acid at 125 mg/kg complete feed is safe for all animal species, but could not conclude on the safety for pigs for fattening at 10 000 mg benzoic acid/kg complete feed. The additive is safe for consumers and the environment but presents a risk for users. Since benzoic acid is authorised in food as flavouring, no further demonstration of efficacy

[14] http://www.efsa.europa.eu/en/efsajournal/pub/4341
[15] http://www.efsa.europa.eu/en/efsajournal/pub/4347
[16] http://www.efsa.europa.eu/en/efsajournal/pub/4345

as flavouring was necessary. The Panel could not conclude on the efficacy as acidity regulator.

The opinion was adopted.[17]

5.14. AXTRA®XB (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for lactating sows and minor porcine species (EFSA-Q-2014-00574)

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 AXTRA®XB (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) as a zootechnical additive for lactating sows and minor porcine species.

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

The opinion was adopted.[18]

5.15. Preparation of *Lactobacillus fermentum* (NCIMB 41636), *Lactobacillus plantarum* (NCIMB 41638) and *Lactobacillus rhamnosus* (NCIMB 41640) (Proccanius) for dogs (EFSA-Q-2014-00588)

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 a preparation of *Lactobacillus fermentum* (NCIMB 41636), *Lactobacillus plantarum* (NCIMB 41638) and *Lactobacillus rhamnosus* (NCIMB 41640) as a technological additive for dogs.

The draft opinion was discussed. The Panel concluded that the additive is safe for dogs, but expressed concerns for the safety of users. The Panel also concluded that the additive is efficacious.

The opinion was adopted.[19]

5.16. Amoklor (ammonium chloride) for cats and dogs, pigs, and ruminants (domestic and wild) (EFSA-Q-2014-00607)

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 Amoklor (ammonium chloride) as a zootechnical additive for cats, dogs and ruminants.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species with certain limitations, is safe

[17] http://www.efsa.europa.eu/en/efsajournal/pub/4353
[18] http://www.efsa.europa.eu/en/efsajournal/pub/4350
[19] http://www.efsa.europa.eu/en/efsajournal/pub/4340

for consumers and environment but expressed concerns for users. The additive is also efficacious.

The opinion was adopted.[20]

5.17. Chemically defined flavourings from Chemical Group 31 - aliphatic and aromatic hydrocarbons: pin-2(10)-ene [01.003], pin-2(3)-ene [01.004], beta-caryophyllene [01.007], myrcene [01.008], camphene [01.009], valencene [01.017], beta-ocimene [01.018] and delta-3-carene [01.029] for all animal species and categories (EFSA-Q-2015-00069)

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 chemically defined flavourings from Chemical Group 31 as sensory additives for all animal species.

The draft opinion was discussed. The Panel concluded that the additives are safe for the target species, the consumer and the environment but expressed concerns for the safety for the users. The Panel also concluded that no demonstration of efficacy was necessary.

The opinion was adopted.[21]

5.18. L-Tryptophan, technically pure for all animal species (EFSA-Q-2015-00251)

The Chair of the WG presented the question and the draft opinion. The European Commission asked EFSA to deliver an opinion on the safety of L-tryptophan produced by fermentation with *Escherichia coli* CGMCC 3667 when used as a nutritional additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. The Panel, based on the new data provided, could not conclude on the safety of the additive for the target species, consumers, users and the environment.

The opinion was adopted.[22]

5.19. L-Threonine, technically pure for all animal species (EFSA-Q-2015-00252)

The Chair of the WG presented the question and the draft opinion. The European Commission asked EFSA to deliver an opinion on the safety of L-threonine produced by fermentation with *Escherichia coli*

[20] http://www.efsa.europa.eu/en/efsajournal/pub/4352
[21] http://www.efsa.europa.eu/en/efsajournal/pub/4339
[22] http://www.efsa.europa.eu/en/efsajournal/pub/4343

CGMCC 3703 when used as a nutritional additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. The Panel, based on the new data provided, concluded that the additive is safe the target species, consumers, users and the environment.

The opinion was adopted.[23]

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, who accepted it:

EFSA-Q-Number	Subject
EFSA-Q-2015-00714	Aviax 5% (Semduramicin sodium) for chickens for fattening
EFSA-Q-2015-00615	ROVABIO® SPIKY (Endo-1,4-ß-xylanase (EC 3.2.1.8) and Endo-1,3(4)-ß-glucanase (EC 3.2.1.6)) for all poultry species (major and minor)
EFSA-Q-2015-00616	Coxiril® (Diclazuril) for chickens reared for laying
EFSA-Q-2015-00618	Coxar® (Nicarbazin) for turkeys for fattening
EFSA-Q-2015-00626	*Lactobacillus rhamnosus* DSM 29226 for all animal species
EFSA-Q-2015-00627	*Lactobacillus plantarum* DSM 29024 for all animal species
EFSA-Q-2015-00652	*Lactobacillus plantarum* DSM 29025 for all animal species
EFSA-Q-2015-00724	*Lactobacillus diolivorans* DSM 32074 for all animal species
EFSA-Q-2015-00732	Natuphos® E 5000 G and Natuphos® E 10000 G (6-phytase) for all pigs and all avian 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-2015-00518	Silicic acid, precipitated and dried (E 551 a) for all animal species	22/10/2015

[23] http://www.efsa.europa.eu/en/efsajournal/pub/4344

This application was assigned to the respective working group.

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

EFSA-Q-Number	Subject
EFSA-Q-2015-00718	Lancer (Lanthanide-citrate) for weaned piglets

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

7.1. Feedback from EFSA

a) In the framework of the Prometheus (Promoting Methods for evidence use in scientific assessments) project, the Panel was asked to compile a survey aimed at collecting potential needs of support for implementing Prometheus, e.g. guidance for all panels/units; training for staff and experts; IT needs; more structured and harmonised approaches to outsourcing data collections/appraisals/syntheses.

b) Kirsten Haupt from the CHAN unit briefly introduced herself as the responsible for risk communication in the area of the FEEDAP Panel.

c) The Head of Unit informed the Panel on the joint session with the ANS Panel that will take place during the next plenary meeting.

7.2. Feedback from the Scientific Committee

a) The Chair of the Panel informed about the topics discussed in the last plenary meeting of the Scientific Committee, among which, the adoption of the opinions on environmental risk assessment.

b) The experts of the Panel were asked to volunteer for the participation to the Standing WG of the Scientific Committee on Guidance update.

8. Other scientific topics for information and/or discussion

a) The Panel discussed the need to develop an up-to-date guidance document for the assessment of additives produced with genetically modified microorganisms. The Panel agreed to ask the Executive Director to task the Panel with a self-task mandate to produce such a guidance document. A specific working group will be established for this task.

b) The Panel also discussed about the need to revise and update the different guidance documents adopted by the Panel regarding the assessment of feed additives. The Panel agreed to request the Executive Director for the endorsement of this self-task. Specific working groups will be established for this task.

9. Any other business

a) The Head of Unit informed the Panel about the outcome of the Annual meeting with the Industry associations held last June. The associations provided EFSA with a list of examples where they consider that EFSA goes beyond its risk assessment role in its opinions.

b) Discussion took place regarding the working methods at working groups and plenary meetings and the different responsibilities of the experts, chairs and rapporteurs. It was agreed that this topic needs further discussion in a future plenary meeting.

c) Gerhard Flachowsky was nominated as Vice-Chair of the Standing WG on Trace elements.