European Food Safety Authority

FEED UNIT

Scientific Panel on Additives and Products or Substances Used in Animal Feed (FEEDAP)

Minutes of the 109th Plenary Meeting

Held on 27-29 January 2015, Parma

(Agreed on 10 March 2015)

Participants

- **Panel Members**

  Gabriele Aquilina, 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, Maria Saarela, Kristen Sejrsen, Patrick van Beelen, John Wallace and Johannes Westendorf.

- **Hearing Experts**

  N/A

- **European Commission**

  N/A

- **EFSA**

  - **FEED Unit:** Manuela Tiramani, Jaume Galobart, Jaime Aguilera, Rosella Brozzi, Anthony Hogan, Orsolya Holczknecht, Oriol Ribó, Jordi Tarrés-Call, Maria Vittoria Vettori and Paola Manini.
  - **REPRO Directorate:** Juliane Kleiner.[1]

- **Observers**

  N/A

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Vasileios Bampidis.

2. Adoption of agenda

The agenda was adopted without modifications.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[2] and the Decision of the Executive Director on Declarations of Interest[3], EFSA

[1] Present only on 27 January AM.

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the FEEDAP 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 108th Plenary meeting held on 9-11 December 2014 (Parma, Italy)

The minutes of the 108th Plenary meeting were reviewed and agreed.[4]

5. Scientific outputs submitted for discussion and possible adoption[5]

5.1. Chemically defined flavourings from Chemical Group 31 - Aliphatic and aromatic hydrocarbons for all animal species and categories (EFSA-Q-2010-00816)

Not discussed due to lack of time.

5.2. Chemically defined flavourings from Chemical Group 05 - Saturated and unsaturated aliphatic secondary alcohols/ketones/ketals/esters with esters containing secondary alcohols. No aromatic or heteroaromatic moiety as a component of an ester or ketal for all animal species and categories (EFSA-Q-2010-01040)

Not discussed due to lack of time.

5.3. Cygro® 10G (maduramicin ammonium) for turkeys (EFSA-Q-2011-00059)

A member 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 Cygro® 10G (maduramicin ammonium) as a coccidiostat for turkeys.

The draft opinion was discussed. The Panel concluded that the additive at the proposed conditions of use is safe for the target species and also for the consumers with a three day withdrawal period. Direct contact of users with the additive should be avoided. The Panel also concluded that the additive is safe for the environment with the exception of soils with pH above 7.2. Efficacy has not been sufficiently demonstrated.

The opinion was adopted.[6]

5.4. Citric acid (preservative) for all animal species (EFSA-Q-2011-00750)

A member 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 citric acid as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe under the proposed conditions of use for the target species, consumers and the environment. It is prudent to regard citric acid as potentially hazardous to workers by exposure to skin, eyes, mucous membranes or by inhalation. Based on the data provided, the efficacy of the additive as a preservative was not sufficiently demonstrated.

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3 http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
4 http://www.efsa.europa.eu/en/events/event/141209-m.pdf
5 During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.
6 http://www.efsa.europa.eu/en/efsajournal/pub/4013.htm

The opinion was adopted.[7]

5.5. L-tryptophan, technically pure for all animal species (EFSA-Q-2011-00948)

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 L-tryptophan produced by a genetically modified strain of *Escherichia coli* 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. The Panel has concerns regarding the safety of the additive when administered via water. Risks for the user might arise form the potential skin sensitisation properties and the content of inhalable endotoxins. The additive is considered an efficacious source of L-tryptophan.

The opinion was adopted.[8]

5.6. L-Lysine (L-lysine monohydrochloride) for all animal species (EFSA-Q-2011-00995)

Not discussed due to lack of time.

5.7. L-Threonine technically pure for all animal species (EFSA-Q-2012-00117)

Not discussed due to lack of time.

5.8. Guanidinoacetic acid (CreAMINO®) for all animal species (EFSA-Q-2012-00273)

The Chair of the WG presented the question. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of guanidinoacetic acid as a nutritional additive for all animal species.

Discussion took place. The Panel identified the need to ask the applicant for clarifications on the data submitted. Therefore, the applicant will be requested to submit additional information.

5.9. Hexamethylene tetramine for pigs, poultry, bovines, ovines, goats, rabbits and horses (EFSA-Q-2012-00415)

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 hexamethylene tetramine as a technological additive for pigs, poultry, bovines, ovines, goats, rabbits and horses.

The draft opinion was discussed. The Panel could not conclude on the safety of the additive for the target species. The additive is considered safe for the consumers and the environment. The additive is irritant to skin, eyes, and mucous membranes, and is a skin and respiratory sensitiser. With the limited data provided the Panel could not conclude on the efficacy of the additive when used alone as silage additive.

The opinion was adopted.[9]

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7 http://www.efsa.europa.eu/en/efsajournal/pub/4009.htm
8 http://www.efsa.europa.eu/en/efsajournal/pub/4015.htm
9 http://www.efsa.europa.eu/en/efsajournal/pub/4014.htm

5.10. DL-Methionyl-DL-methionine for all aquatic species (EFSA-Q-2012-00942)

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 DL-Methionyl-DL-Methionine as a nutritional additive for all aquatic species.

The draft opinion was discussed. The Panel concluded that the additive is safe for fish and crustaceans, for the consumer, the user and the environment. The Panel also concluded that the additive is an efficacious source of the amino acid L-methionine.

The opinion was adopted.[10]

5.11. XTRACT® Evolution-B (Carvacrol, cinnamaldehyde, capsicum oleoresin) for chickens for fattening (EFSA-Q-2013-00583)

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 XTRACT® Evolution-B (carvacrol, cinnamaldehyde, capsicum oleoresin) as a zootechnical additive for chickens for fattening.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target animals, consumers and the environment. The additive should be considered a skin, eye and respiratory tract irritant and a skin sensitiser. The Panel also concluded that the additive has the potential to be efficacious in chickens for fattening.

The opinion was adopted.[11]

5.12. Citric acid (acidity regulator) for all animal species (EFSA-Q-2013-00612)

A member 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 citric acid as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe under the proposed conditions of use for the target species, consumers and the environment. It is prudent to regard citric acid as potentially hazardous to workers by exposure to skin, eyes, mucous membranes or by inhalation. The Panel also concluded that citric acid might have the potential to act as an acidity regulator in feedingstuffs.

The opinion was adopted.[12]

5.13. Cibenza® EP150 (Preparation of protease, EC 3.4.21.19 and *Bacillus licheniformis*, ATCC 53757) for chickens for fattening, chickens reared for laying, poultry and game birds for fattening and reared for laying excluding laying birds, ornamental birds and sporting birds for fattening and reared for laying excluding laying birds (minor avian species for fattening and to point of lay: ducks, geese, pigeons and other game birds, ornamental and sporting birds) (EFSA-Q-2013-00630)

Not discussed due to lack of time.

5.14. L-Valine for all animal species (EFSA-Q-2014-00299)

Not discussed due to lack of time.

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10 http://www.efsa.europa.eu/en/efsajournal/pub/4012.htm
11 http://www.efsa.europa.eu/en/efsajournal/pub/4011.htm
12 http://www.efsa.europa.eu/en/efsajournal/pub/4010.htm

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 them:

EFSA-Q-Number	Subject
EFSA-Q-2014-00888	Natrolite-phonolite (PHIL 75®) for all animal species
EFSA-Q-2014-00887	Silicic acid, precipitated and dried, and Colloidal silica for all animal species
EFSA-Q-2014-00890	Natrolith-Phonolith for animal species
EFSA-Q-2014-00886	Synthetic calcium silicate for all animal species
EFSA-Q-2014-00889	Ethyl Cellulose for all animal species
EFSA-Q-2014-00829	Optiphos® G4000, Optiphos® CT 4000, Optiphos® L8000 (6-phytase) for pigs for fattening
EFSA-Q-2014-00909	Cumin tincture for all animal species
EFSA-Q-2014-00900	Fumonisin esterase (FUMzyme®) for all avian species and all pigs
EFSA-Q-2015-00004	Calsporin® (*Bacillus subtilis* C-3102) for dogs
EFSA-Q-2015-00005	Calsporin® (*Bacillus subtilis* C-3102) for laying hens, minor avian species (game birds, ducks, geese, pigeons, sporting & ornamental birds) for laying.
EFSA-Q-2015-00054	Natuphos® E 5000, Natuphos® E 5000 L, Natuphos® E 10000 L, Natuphos® E 25000 L (6-phytase) for all avian species and all pigs
EFSA-Q-2015-00032	Maxiban G160 (Narasin 80 g activity/kg and Nicarbazin 80 g/kg.) for chickens for fattening
EFSA-Q-2015-00053	Preparation of algae interspaced bentonite for all animal species
EFSA-Q-2015-00033	Monteban™ G100 (granular narasin, equivalent to 100g narasin activity) for ducks

6.2. New questions under Regulation (EC) No 178/2002

EFSA-Q-Number	Subject
EFSA-Q-2014-00903	Preparation of bentonite-montmorillonite and sepiolite (Toxfin® Dry) for all animal species
EFSA-Q-2015-00055	Fecinor® and Fecinor® Plus (*Enterococcus faecium* CECT 4515) for piglets (weaned)

6.3. 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
1	EFSA-Q-2014-00455	Lecithins for all animal species	01/12/2014
2	EFSA-Q-2014-00350	Salinomax® 120G (salinomycin sodium) for chickens for fattening	03/12/2014
3	EFSA-Q-2014-00506	Sodium selenate for all animal species	04/12/2014
4	EFSA-Q-2014-00505	Sodium selenite (Retosel 100 sd) for all animal species	04/12/2014
5	EFSA-Q-2014-00629	Dicopper oxide for all animal species	15/12/2014
6	EFSA-Q-2014-00635	L-glutamine for horses (non food producing) and dogs	18/12/2014
7	EFSA-Q-2014-00457	Perlite for ruminants and poultry	18/12/2014
8	EFSA-Q-2014-00464	Lipidol Lecithin (LIPIDOL) for all animal species	15/01/2015

These applications were assigned to the respective working groups.

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

a. The Panel was informed on the “Info session” in the area of feed that will be organised on 5-6 May 2015 in Barcelona.

b. The Scientific Committee requested the Panel for volunteers for the WG on Benchmark dose, Weight of evidence and Biological relevance.

c. The Panel provided feedback on the use of the document management system in place.

8. Other scientific topics for information and/or discussion

a. A discussion took place regarding the presence of substances with genotoxic-carcinogenic properties, like estragole and methyl eugenol, in feed additives. These substances are components of essential oils of botanical origin, like star anise oil and clove oil. The Panel stated that the intentional addition of such substances to the food chain via feed additives is not acceptable. This applies independently from the origin of the substances (chemical synthesis or botanical origin).

9. Any other business

The Head of the REPRO department, Juliane Kleiner, introduced herself to the Panel.