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

Minutes of the 107th Plenary Meeting

Held on 28-30 October 2014, Parma

(Agreed on 9 December 2014)

Participants

- **Panel Members**

  Gabriele Aquilina, Vasileios Bampidis, Maria De Lourdes Bastos, Gerhard Flachowsky, Mikolaj Antoni Gralak, Christer Hogstrand, Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Fernando Ramos, Derek Renshaw, Guido Rychen, Kristen Sejrsen, John Wallace and Johannes Westendorf.

- **Hearing Experts**

  Alberto Mantovani[1]

- **European Commission**

  N/A

- **EFSA**

  - **FEED Unit:** Claudia Roncancio-Peña, Jaume Galobart, Jaime Aguilera, Rosella Brozzi, Matteo Lorenzo Innocenti, Oriol Ribó, Jordi Tarrés-Call, Maria Vittoria Vettori and Anthony Hogan.
  - **REPRO Directorate:** Per Bergman[2]
  - **AMU Unit:** Elisa Aiassa[3]

- **Observers**

  N/A

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Lucio Guido Costa, Maria Saarela and Patrick van Beelen.

2. Adoption of agenda

The agenda was adopted after the removal of the items "Cylactin®/Cernivet® (*Enterococcus faecium* NCIMB 10415) for piglets (suckling and weaned), pigs for fattening and sows

[1] Present only on 29 October for item 5.1.
[2] Present only on 28 October for item 7b.
[3] Present only on 29 October for item 7c.

(EFSA-Q-2012-00419)" and "Formic acid, ammonium formate and sodium formate for all animal species (EFSA-Q-2013-00755)".

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[4] and the Decision of the Executive Director on Declarations of Interest[5], EFSA 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 106th Plenary meeting held on 9-11 September 2014 (Parma, Italy)

The minutes of the 106th Plenary meeting were reviewed and agreed.[6]

5. Scientific outputs submitted for discussion and possible adoption[7]

5.1. Suilectin™ (Lectins isolated from kidney bean - *Phaseolus vulgaris*) for piglets (suckling) (EFSA-Q-2010-01044)

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 Suilectin™ (lectins isolated from kidney beans) as a zootechnical additive for suckling piglets.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target animals, consumer and the environment. Hazards for users are limited to potential respiratory sensitization. With the data available, the Panel could not conclude on the efficacy of this product.

The opinion was adopted.

5.2. Friedland clay (montmorillonite-illite mixed layer clay) for all animal species (EFSA-Q-2011-00280)

A member 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 Friedland clay (montmorillonite-illite mixed layer clay) as a technological 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 is considered a potential skin and eye irritant, a skin sensitiser and a hazard by inhalation. The Panel could not conclude on the efficacy of the product.

The opinion was adopted.[8]

4 http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
5 http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
6 http://www.efsa.europa.eu/en/events/event/140909-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/3904.htm

5.3. Calcium formate for all animal species (EFSA-Q-2011-00423)

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 calcium formate as a technological 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 additive is not irritant to skin but causes adverse effects to eyes. It is likely that handling the additive could result in skin reactions and in the production of respirable dust that could present a risk to unprotected workers. The Panel could not conclude on the efficacy of the product.

The opinion was adopted.[9]

5.4. Cassia gum for dogs and cats (EFSA-Q-2012-00119)

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 cassia gum as a technological additive for dogs and cats.

The draft opinion was discussed. The Panel concluded that only purified semi-refined cassia gum corresponding to the specifications of cassia gum as food additive can be considered safe for cats and dogs, at a maximum content of 13200 mg/kg complete feed. The additive is considered a potential skin and eye irritant and as a skin and respiratory sensitiser. The efficacy of cassia gum alone was not demonstrated, but it has the potential to be effective as a gelling agent when used together with carrageenan.

The opinion was adopted.[10]

5.5. Cassia gum (Galactogum) for dogs and cats (EFSA-Q-2012-00120)

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 cassia gum as a technological additive for dogs and cats.

The draft opinion was discussed. The Panel concluded that only purified semi-refined cassia gum corresponding to the specifications of cassia gum as food additive can be considered safe for cats and dogs, at a maximum content of 13200 mg/kg complete feed. It would be prudent to assume that cassia gum has the potential to harm workers who might be exposed by skin, eyes or inhalation. The Panel could not conclude on the efficacy of cassia gum as gelling agent and thickener.

The opinion was adopted.[11]

5.6. Cassia gum for dogs and cats (EFSA-Q-2012-00121)

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 cassia gum as a technological additive for dogs and cats.

The draft opinion was discussed. The Panel concluded that only purified semi-refined cassia gum corresponding to the specifications of cassia gum as food additive can be considered safe for cats and dogs, at a maximum content of 13200 mg/kg complete feed. It would be prudent to assume that cassia gum has the potential to harm workers

9 http://www.efsa.europa.eu/en/efsajournal/pub/3898.htm
10 http://www.efsa.europa.eu/en/efsajournal/pub/3899.htm
11 http://www.efsa.europa.eu/en/efsajournal/pub/3900.htm

who might be exposed by skin, eyes or inhalation. The Panel could not conclude on the efficacy of cassia gum as gelling agent and thickener.

The opinion was adopted.[12]

5.7. Cassia gum (Diagum™ CS) for dogs and cats (EFSA-Q-2012-00122)

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 cassia gum as a technological additive for dogs and cats.

The draft opinion as discussed. The Panel concluded that only purified semi-refined cassia gum corresponding to the specifications of cassia gum as food additive can be considered safe for cats and dogs, at a maximum content of 13200 mg/kg complete feed. The additive is considered a potential skin and eye irritant and as a skin and respiratory sensitiser. The efficacy of cassia gum alone was not demonstrated, but it has the potential to be effective as a gelling agent and thickener when used together with other hydrocolloids (e.g., carrageenan, xanthan gum) and as a stabiliser.

The opinion was adopted.[13]

5.8. L-Valine for all animal species (EFSA-Q-2012-00694)

Not discussed due to lack of time.

5.9. DL-Methionyl-DL-Methionine for all aquatic animal species (EFSA-Q-2012-00942)

Not discussed due to lack of time.

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

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

The draft opinion as discussed. The Panel identified some issues that required further clarifications and agreed to ask the applicant to provide additional information.

5.11. AGal-Pro BL-L (alpha-galactosidase and endo-1,4-beta-glucanase) for chickens for fattening (EFSA-Q-2013-00581)

The Chair of the WG presented the question and the draft opinion. This question refers to the modification of the terms of authorisation of the additive AGal-Pro BL-L (alpha-galactosidase and endo-1,4-beta-glucanase) as a zootechnical additive for chickens for fattening. The applicant is nseeking the authorisation of a new liquid formulation of the additive.

The draft opinion was discussed. The Panel concluded that AGal-Pro BL-L is safe and efficacious for the target species and is safe for the consumer and the environment. The additive is an irritant to skin and eyes, a dermal sensitiser and should be considered a respiratory sensitiser.

The opinion was adopted.[14]

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12 http://www.efsa.europa.eu/en/efsajournal/pub/3901.htm
13 http://www.efsa.europa.eu/en/efsajournal/pub/3902.htm

5.12. Astaxanthin-rich *Phaffia rhodozyma* KBW 10061 (AJ14971) (Ajinomoto Phaffia Astaxanthin) for salmon and trout (EFSA-Q-2013-00770)

Not discussed due to lack of time.

5.13. Coxiril® (diclazuril) for rabbits for fattening and breeding does (EFSA-Q-2013-00815)

Not discussed due to lack of time.

5.14. L-Lysine-monohydrochloride (L-lysine min 78%)/Concentrated Liquid L-lysine (Base) (L-lysine min 50%)/Concentrated Liquid L-lysine-monohydrochloride (L-lysine min 22.4%) for all animal species (EFSA-Q-2013-00823)

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 three products based on L-lysine produced by the genetically modified *Escherichia coli* (FERM BP-11355) as a nutritional additive 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. Concerns for user safety are limited to a potential for respiratory sensitisation. The three additives are considered an efficacious source of L-lysine for all non-ruminant species. For ruminants, a protected form should be used.

The opinion was adopted.[15]

5.15. CRINA® Poultry Plus (benzoic acid, thymol, eugenol and piperine) for chickens for fattening, chickens reared for laying, minor poultry species (for fattening and reared for laying) (EFSA-Q-2013-00977)

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 CRINA® Poultry Plus (benzoic acid, thymol, eugenol and piperine) as a zootechnical additive for chickens for fattening, chickens reared for laying, minor poultry species (for fattening and reared for laying).

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumer and the environment and has the potential to be efficacious.

The opinion was adopted.[16]

5.16. Biomin® C3 (*Bifidobacterium animalis* ssp. *animalis*, *Lactobacillus salivarius* ssp. *salivarius* and *Enterococcus faecium*) as feed additive for chickens for fattening, chickens reared for laying and minor avian species other than laying species (EFSA-Q-2014-00224)

Not discussed due to lack of time.

14 http://www.efsa.europa.eu/en/efsajournal/pub/3897.htm
15 http://www.efsa.europa.eu/en/efsajournal/pub/3895.htm
16 http://www.efsa.europa.eu/en/efsajournal/pub/3896.htm

5.17. Cylactin® or Cernivet® LBC ME10, LBC ME20 Plus (*Enterococcus faecium* NCIMB 10415) for chickens for fattening, chickens reared for laying, minor poultry species (for fattening and reared for laying) (EFSA-Q-2014-00234)

A member of the WG presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the modification of the terms of authorisation under Article 13 of Regulation (EC) No 1831/2003 of Cylactin® (*Enterococcus faecium* NCIMB 10415) as a zootechnical additive for chickens for fattening, chickens reared for laying, minor poultry species (for fattening and reared for laying).

The draft opinion was discussed. The Panel concluded that the additive is safe and efficacious in the target species. The active agent was found to be compatible with a number of coccidiostats.

The opinion was adopted.[17]

5.18. Avi-Deccox 60 G (decoquinate) for chickens for fattening (EFSA-Q-2014-00290)

A member of the WG presented the question and the draft opinion. This question refers to the modification of the terms of authorisation under Article 13 of Regulation (EC) No 1831/2003 of Avi-Deccox 60 G (decoquinate) as a coccidiostat for chickens for fattening.

The draft opinion was discussed. The Panel concluded that proposed modifications in the composition and physical form of the additive will not affect its safety for target species, consumer, user and environment nor its efficacy with respect of the currently authorised form.

The opinion was adopted.[18]

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-2014-00607	AMOKLOR (Ammonium chloride) for all animal species
EFSA-Q-2014-00629	Dicopper oxide for all animal species
EFSA-Q-2014-00634	Natural mixtures of talc and chlorite for all animal species
EFSA-Q-2014-00635	L-glutamine for horses (non food producing) and dogs
EFSA-Q-2014-00636	Betaine anhydrous for all animal species
EFSA-Q-2014-00666	MAXIBAN® G160 (narasin and nicarbazin)
EFSA-Q-2014-00729	*Bacillus subtilis* (DSM 27273)

17 http://www.efsa.europa.eu/en/efsajournal/pub/3906.htm
18 http://www.efsa.europa.eu/en/efsajournal/pub/3905.htm

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

EFSA-Q-Number	Subject
EFSA-Q-2014-00503	Amylofeed® (endo-1,3(4)-beta-glucanase, endo-1,4-beta-xylanase and alpha-amylase) for weaned piglets and young minor porcine species

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-2014-00496	Zinc chelate from L-Lysinate HCl (Aminotrace Zinc Bislysinate) for all animal species	16/09/2014
2	EFSA-Q-2014-00574	AXTRA® XB 201 (endo-1,4 beta-xylanase and endo-1,3(4)-beta-glucanase) for minor porcine species for meat production, sows for reproduction, minor porcine species for reproduction	23/09/2014
3	EFSA-Q-2014-00352	Benzoic acid for all animal species	23/09/2014
4	EFSA-Q-2014-00296	L-Arginine produced by fermentation with *Corynebacterium glutamicum* KCTC 10423 BP for all animal species	02/10/2014
5	EFSA-Q-2014-00587	*Bacillus subtilis* PB6 (*Bacillus subtilis*) for sows	07/10/2014
6	EFSA-Q-2014-00227	Levucell SB 20/SB 10 ME/Titan (*Saccharomyces cerevisiae* CNCM I-1079) for sows and piglets	09/10/2014
7	EFSA-Q-2014-00375	Levucell SC 20, Levucell SC10 ME and/or Titan (*Saccharomyces cerevisiae* CNCM I-1077) for dairy cows, cattle for fattening	09/10/2014
8	EFSA-Q-2014-00507	Sodium selenite for all animal species	21/10/2014

These applications were assigned to the working groups on Trace elements (#1 & 8), Enzymes (#2), Organic acids (#3), Amino acids (#4) and Microorganisms (#5-7).

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

a. Dr. Per Bergman, Head of the Repro Department informed the Panel of the following issues:

- He will leave EFSA as of 30 November to join the Swedish Food Safety Agency, as Head of Risk Assessment.
- Claudia Roncancio-Peña will take the position of Head of Unit of the FIP Unit, and Manuela Tiramani will act as Head of the FEED Unit as interim.

- A new policy of declarations of interest will take effect as of 1st December. The Panel was informed on the main changes in the policy.

b. A member of the AMU unit made a presentation regarding the project Prometheus.

c. The Panel was also informed on the new data management system that will be implemented in EFSA.

8. Other scientific topics for information and/or discussion

a. The Panel discussed a proposal from the WG on Enzymes regarding the assessment of efficacy for phytases. The Outcome of the discussion is detailed in Annex 1.

9. Any other business

The date for the Plenary meeting of June 2015 has been changed to 16-18 June 2015.

Annex 1

Efficacy assessment of phytases

According to Section IV of the EFSA Guidance on Zootechnical additives (EFSA FEEDAP Panel, 2011) *"All studies for demonstration of the efficacy of phytases can be designed as short-term studies provided that digestibility of phytate/total P and partial (e.g., bone ash/P) or total P retention are included as end-points. Ileal digestibility measurements are not encouraged"*.

In the case of sows, welfare and technical aspects should be considered and therefore, (faecal) digestibility trials could be accepted.

The FEEDAP Panel agreed on the following:

All studies for demonstration of the efficacy of phytases can be designed as short-term studies provided that digestibility of phytate/total P and partial (e.g., bone ash/P) or total P retention are included as end-points. Studies in which the effect of a phytase is only measured as the faecal digestibility of total phosphorus will not be accepted as proof of efficacy. Ileal digestibility measurements will not be accepted anymore.

As an exception from the above, and considering ethical and technical reasons, the Panel may accept the study of the faecal digestibility of total phosphorus in sows.

Further considerations:

Sows:

- For applications in sows covering the whole productive cycle (gestating and lactating), at least one study should be performed in lactating sows.
- In lactating sows, the additive should be offered during the whole lactation and the performance of the litter during the lactation should be reported in order to show the absence of adverse effects.

Laying hens:

- Phosphorus balances studies in laying poultry should include the measurement of P in excreta and in the egg. Indeed, supplementation of layer hens diets with microbial phytase allows to reduce non-phytate phosphorus in the diet, and consequently phosphorus excretion (Selle and Ravindran, 2007; Bouvarel et al., 2011), with possible impact on phosphorus content of eggs (Kovács et al., 2006).
- Laying intensity of the hens before (minimum two weeks) and during the balance period should be recorded in order to show the absence of adverse effects.

References

Bouvarel, I., Nys, Y., Lescoat, P., 2011. Ch. 12. Hen nutrition for sustained egg quality. In: Nys, Y., Bain, M., Van Immerseel, F. (Eds.), Improving the Safety and Quality of Eggs and Egg Products, Vol. 1: Egg Chemistry, Production and Consumption, pp. 262–299. Woodhead Publishing Series in Food Science, Technology and Nutrition: Number 213, Woodhead Publishing Ltd., Cambridge, UK.

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Guidance for the preparation of dossiers for zootechnical additives. EFSA Journal 2012;10(1):2536. [19 pp.]

Kovács, KR., Tossenberger, J., Babinszky, L., 2006. Effect of different phosphorus intakes on phosphorus balance and performance of layers during peak production. Acta Agraria Kaposváriensis 10, 193–198.

Selle, P.H., Ravindran, V., 2007. Microbial phytase in poultry nutrition. Animal Feed Science and Technology 135, 1–41.