European Food Safety Authority

FEED UNIT

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

Minutes of the 106th Plenary Meeting

Held on 9-11 September 2014, Parma

(Agreed on 28 October 2014)

These minutes replace an earlier version following an editorial amendment that does not affect their contents or outcome. To avoid confusion, the original version has been removed from the EFSA website.

Participants

- **Panel Members**

  Gabriele Aquilina, Vasileios Bampidis, Maria De Lourdes Bastos,[1] Lucio Guido Costa, Gerhard Flachowsky, Mikolaj Antoni Gralak, Christer Hogstrand,[2] Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Fernando Ramos,[3] Derek Renshaw, Guido Rychen, Maria Saarela, Kristen Sejrsen, Patrick van Beelen, John Wallace and Johannes Westendorf.

- **Hearing Experts**[4]

  Alberto Mantovani[5]

- **European Commission**

  N/A

- **EFSA**

  - **FEED Unit:** Claudia Roncancio-Peña, Jaume Galobart, Jaime Aguilera, Rosella Brozzi, Lucilla Gregoretti, Matteo Lorenzo Innocenti, Jordi Tarrés-Call and Maria Vittoria Vettori.

- **Observers**

  N/A

1. Welcome and apologies for absence

The Chair welcomed the participants. No Apologies were received.

2. Adoption of agenda

The agenda was adopted after the removal of the item “AGal-Pro BL-L (Alpha-Galactosidase and endo-1,4-beta-glucanase) for chickens for fattening (EFSA-Q-2013-00581)”.

---

[1] Present only on 10-11 September.
[2] Present only on 9-10 September.
[3] Present only on 10-11 September.
[4] As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf
[5] Present only on 10 September for item 5.2.

3. Declarations of interest

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 (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I. Oral Declaration of Interests was asked at the beginning of the meeting and no additional interests were declared.

4. Agreement of the minutes of the 105th Plenary meeting held on 1-3 July 2014

The minutes of the 105th Plenary meeting were reviewed and agreed.[8]

5. Scientific outputs submitted for discussion and possible adoption[9]

5.1. BioPlus® 2B (*Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750) for piglets, pigs for fattening, sows, turkeys for fattening and calves (EFSA-Q-2009-00680)

Not discussed due to lack of time.

5.2. 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 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 identified some issues that required further discussion and asked the WG to provide an updated draft to the next plenary meeting.

5.3. 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)

Not discussed due to lack of time.

5.4. Tannic acid for all animal species and categories (EFSA-Q-2010-01513)

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of tannic acid as a sensory additive for all animal species.

The draft opinion was discussed. The Panel concluded that tannic acid is safe for the target animals, the consumers and the environment. However, it should be regarded as potentially hazardous to workers. The Panel also concluded that, since its function in feed is essentially the same as in food, no demonstration of efficacy is needed.

The opinion was adopted.[10]

---

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/en/events/event/140701-m.pdf
9 During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.
10 http://www.efsa.europa.eu/en/efsajournal/pub/3828.htm

5.5. Bentonite-Montmorillonite (FIMIX) for all animal species (EFSA-Q-2011-00280)

Not discussed due to lack of time.

5.6. Formic acid for all animal species (EFSA-Q-2011-00421)

A member of the working group (WG) presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of formic acid as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that the formic acid is safe for the target species at the proposed conditions of use, but a margin of safety could not be identified. The additive is also considered safe for the consumer and for the environment. Exposure of users by skin, eyes or inhalation is considered a risk. The Panel also concluded that formic acid at the recommended levels inhibits bacterial growth in feedingstuffs and water for drinking and is an efficacious silage additive.

The opinion was adopted.[11]

5.7. Zinc (zinc acetate, dihydrate; zinc chloride, anhydrous; zinc oxide; zinc sulphate, heptahydrate; zinc sulphate, monohydrate; zinc chelate of amino acids, hydrate; zinc chelate of glycine, hydrate (solid); zinc chelate of glycine, hydrate (liquid)) for all animal species (EFSA-Q-2011-00845)

Not discussed due to lack of time.

5.8. Cylactin®/Cernivet® (*Enterococcus faecium* NCIMB 10415) for piglets (suckling and weaned), pigs for fattening and sows (EFSA-Q-2012-00419)

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)

Not discussed due to lack of time.

5.11. MycoCell (*Saccharomyces cerevisiae* NCYC R404) for dairy cows for milk production (EFSA-Q-2013-00205)

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 MycoCell (*Saccharomyces cerevisiae* NCYC R404) as a zootechnical additive for dairy cows.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumer and the environment. It is not a skin or eye irritant but it is a skin sensitiser. The Panel also concluded that the additive has the potential to be efficacious.

The opinion was adopted.[12]

[11] http://www.efsa.europa.eu/en/efsajournal/pub/3827.htm
[12] http://www.efsa.europa.eu/en/efsajournal/pub/3830.htm

5.12. L-threonine (technically pure) for all animal species (EFSA-Q-2013-00676)

The Chair of the WG presented the question and the draft opinion. This question refers to the authorisation under Article 4 of L-threonine technically pure produced by a genetically modified strain of *Escherichia coli* (FERM BP-11383) as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that the genetic modifications do not raise any safety concern. Moreover, the Panel concluded that L-threonine technically pure is safe for the target animals, consumers, users and the environment and is an effective source of the amino acid L-threonine.

The opinion was adopted.[13]

5.13. L-tryptophan (technically pure) for all animal species (EFSA-Q-2013-00677)

The Chair of the WG presented the question and the draft opinion. This question refers to the authorisation under Article 4 of L-tryptophan technically pure produced by a genetically modified strain of *Escherichia coli* (FERM BP-11354) as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that the genetic modifications do not raise any safety concern. Moreover, the Panel concluded that L-threonine technically pure is safe for the target animals, consumers, users and the environment and is an effective source of the amino acid L-threonine.

The opinion was adopted.[14]

5.14. *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237 for all animal species (EFSA-Q-2013-00735)

The Chair of the WG presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the efficacy of *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237 as silage additives based on the additional date provided by the applicant.

The draft opinion was discussed. Based on the new data provided, the Panel concluded that the strains used in combination have the potential to improve the preservation of nutrients in silage from all forages.

The opinion was adopted.[15]

5.15. Coxiril (Diclazuril) for rabbits for fattening and breeding does (EFSA-Q-2013-00815)

Not discussed due to lack of time.

5.16. 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

[13] http://www.efsa.europa.eu/en/efsajournal/pub/3825.htm
[14] http://www.efsa.europa.eu/en/efsajournal/pub/3825.htm
[15] http://www.efsa.europa.eu/en/efsajournal/pub/3829.htm

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 identified some issues that required further discussion and asked the WG to provide an updated draft to the next plenary meeting.

5.17. 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)

Not discussed due to lack of time.

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-2014-00505	Sodium selenite (Retosel 100 sd) for all animal species
EFSA-Q-2014-00506	Sodium selenate for all animal species
EFSA-Q-2014-00507	Sodium selenite for all animal species
EFSA-Q-2014-00508	Sodium selenite (film granulated preparation) for all animal species
EFSA-Q-2014-00496	Zinc chelate from L-Lysinate HCl (Aminotrace Zinc Bislysinate) for all animal species
EFSA-Q-2014-00588	Preparation of Lactobacillus fermentum NCIMB 41636, Lactobacillus plantarum NCIMB 41638, Lactobacillus rhamnosus NCIMB 41640 (Proccanius) for dogs
EFSA-Q-2014-00574	Axtra® XB (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
EFSA-Q-2014-00575	Fra Octazyme C Dry and Fra Octazyme C Liquid (alphagalactosidase (3.2.1.22), alpha-amylase (3.1.1), endo-l,3(4)-beta-glucanase (3.2.1.6), endo-l,4-beta-glucanase (3.2.14), mannan-endo-1,4-beta-mannosidase (3.2.1.78), pectinase, protease (3.4.21.62), endo-1,4-beta-xylanase (3.2.1.8)) for piglets (weaned), chickens for fattening
EFSA-Q-2014-00586	Bergazym® P 100 (endo-1,4-beta-xylanase) for chickens for fattening, piglets (weaned), pigs for fattening
EFSA-Q-2014-00587	*Bacillus subtilis* PB6 (*Bacillus subtilis* ATCC PTA-6737) for sows, in order to have benefits in piglets

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

EFSA-Q-Number	Subject
EFSA-Q-2014-00551	VevoVitall® (benzoic acid) for pigs for reproduction (gestating and lactating sows, gilts and boars)
EFSA-Q-2014-00573	Prostora Max (*Bifidobacterium animalis* AHC7 (NCIMB 41617)) for dogs

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-2013-01021	Xanthan gum for all animal species	03/07/2014
2	EFSA-Q-2014-00450	Ronozyme® NP (CT), Ronozyme® NP (L), Ronozyme® NP(M)(6-phytase (IUB / EC 3.1.3.26) for pigs for fattening.	30/07/2014
3	EFSA-Q-2013-00996	Lavipan (*Lactobacillus lactis* IBB500, *Carnobacterium divergens* S1, *Lactobacillus casei* LOCK 0915, *Lactobacillus plantarum* LOCK 0862, *Saccharomyces cerevisiae* LOCK 0141) for piglets (weaned), chickens for fattening, turkeys for fattening	31/07/2014
4	EFSA-Q-2014-00463	Rovabio® Spiky (endo-1,4-beta-xylanase EC 3.2.1.8 and endo-1,3(4)-beta-glucanase EC 3.2.1.6) for all major and minor poultry species (for fattening, reared for laying and breeding)	01/08/2014
5	EFSA-Q-2013-01029	Ronozyme® HiPhos (GT),(L),(M),(6-phytase) for sows for reproduction, sows, in order to have benefit in piglets, fish salmonids, sea bream, tilapia, shrimps	01/08/2014
6	EFSA-Q-2014-00289	Primary Smoke Condensate-Smoke Flavouring (SmokEz C-10) for cats and dogs	01/08/2014
7	EFSA-Q-2013-01024	Guar gum for all animal species	06/08/2014
8	EFSA-Q-2013-01022	Acacia gum, Gum arabic for all animal species	06/08/2014
9	EFSA-Q-2013-01020	Tragacanth gum for all animal species	06/08/2014
10	EFSA-Q-2014-00219	Aviax 5% (Semduramicin sodium) for chickens for fattening	14/08/2014
11	EFSA-Q-2013-00976	Robenz® 66G (Robenidine hydrochloride (E758)) for chickens for fattening and turkeys for fattening	18/08/2014

These applications were assigned to the working groups on Technological additives (#1, 7, 8 & 9), Enzymes (#2, 4 & 5), Microorganisms (#3), Feed flavourings (#6) and Coccidiostats (#10 & 11).

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

a. The Panel discussed the interpretation of the Earthworm Reproduction Test (OECD test guideline 222). This issue will be further discussed in a future meeting.

b. The Panel was informed that the WG on Colourings asked assistance to the Standing WG on Genotoxicity of the Scientific Committee with regards to the assessment of Brilliant Black.

c. The WG on Silage additives requested input from the Panel on the safety assessment of a silage additive.

d. The Panel members were invited to participate to the WG on Emerging Risks of the Scientific Committee and to the EFSA WG on Prometheus.

e. The Panel was also requested to provide input regarding the identification of areas/tasks susceptible to be outsourced.

f. The Panel provided feedback on the Matrix project as requested by EFSA.

8. Other scientific topics for information and/or discussion

Not discussed

9. Any other business

Not discussed

Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)

a) In the SDoI filled for the present meeting Prof. John Wallace declared the following interest: he has a current ad-hoc consultancy and research activities with the applicant of BioPlus 2B (item 5.1). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[16] and the Decision of the Executive Director on Declarations of Interest,[17] and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when that item (5.1) is discussed, voted on or in anyway processed by that concerned scientific group.

[16] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[17] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf