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

Minutes of the 105th Plenary Meeting

Held on 1-3 July 2014, Parma

(Agreed on 9 September 2014)

Participants

- **Panel Members**

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

- **Hearing Experts**

  N/A

- **European Commission**

  N/A

- **EFSA**

  - **FEED Unit:** Claudia Roncancio-Peña, Jaume Galobart, Jaime Aguilera, Montserrat Anguita, Rosella Brozzi, Lucilla Gregoretti, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini, Oriol Ribó and Jordi Tarrés-Call.
  - **Repro Department:** Per Bergman[2]
  - **EXO Unit:** Roy Kirby[3]

- **Observers**

  N/A

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Christer Hogstrand and Patrick van Beelen.

2. Adoption of agenda

The agenda was adopted without changes.

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1 Present only on 1-2 July.
2 Present only on 2 July for item 7.a.
3 Present only on 2 July for item 7.b.

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 implementing this Policy regarding Declarations of Interests,[5] EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the experts invited for the present meeting. No conflicts of interests 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 104th Plenary meeting held on 20-22 May 2014

The minutes of the 104th Plenary meeting were reviewed and agreed.[6]

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

5.1. 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)

A member of the working group (WG) presented the question. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of vitamin B2 as a nutritional additive for all animal species.

A short discussion took place. The opinion will be discussed in detail in a future plenary meeting.

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

5.3. *Lactobacillus acidophilus* D2/CSL for laying hens (EFSA-Q-2011-00205)

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 *Lactobacillus acidophilus* D2/CSL as a zootechnical additive for laying hens.

The draft opinion was discussed. The Panel concluded that *Lactobacillus acidophilus* D2/CSL is safe for the target species, consumers and the environment. Concerns for users regard its potential for eye/skin irritation and skin/respiratory sensitisation. The Panel also concluded that the additive has the potential to be efficacious in laying hens.

The opinion was adopted.[8]

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4 http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
5 http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
6 http://www.efsa.europa.eu/en/events/event/140520-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/3789.htm

5.4. Sorbic acid and potassium sorbate for all animal species (EFSA-Q-2011-00840)

A member of the 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 sorbic acid and potassium sorbate as technological additives for all animal species.

The draft opinion was discussed. The Panel concluded that sorbic acid and its potassium salt are safe for the target species, consumers and the environment when used at the maximum proposed level in feed. These additives are skin, eye and respiratory irritants. As both substances are authorised as preservatives in food, it is reasonable to expect that the same effect will be observed in feed. The Panel expressed its reservations about their effectiveness in complete feedingstuffs with a moisture content of ≤ 12 %.

The opinion was adopted.[9]

5.5. L-valine feed grade (ValAMINO®) for all animal species (EFSA-Q-2012-00377)

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-valine feed grade as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that L-valine produced by the specific strain of *Corynebacterium glutamicum* (DSM 25202) is safe for the target species, consumers and the environment. It would be prudent to consider it as a skin/eye irritant, a potential dermal sensitiser and potentially harmful by inhalation. It is an efficacious source of supplemented amino acid for all species but with a low efficiency in ruminants unless it is used in a protected form.

The opinion was adopted.[10]

5.6. AviMatrix (benzoic acid, calcium formate and fumaric acid) for chickens for fattening, chickens reared for laying, minor avian species for fattening and to point of lay (EFSA-Q-2013-00072)

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 AviMatrix (benzoic acid, calcium formate and fumaric acid) as a zootechnical additive for chickens for fattening, chickens reared for laying, minor avian species for fattening and to point of lay.

The draft opinion was discussed. Following the discussion, the opinion was adopted modified accordingly.

5.7. Copper chelate of L-Lysinate-HCl (Aminotrace Copper Bislysinate) for all animal species (EFSA-Q-2013-00407)

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 copper chelate of L-Lysinate-HCl 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, consumers and the environment, provided that the maximum copper

[9] http://www.efsa.europa.eu/en/efsajournal/pub/3792.htm
[10] http://www.efsa.europa.eu/en/efsajournal/pub/3795.htm

contents authorised in feed are respected. Both powder and granulate forms are regarded as potential skin sensitisers while the powder form is also an eye irritant. A risk by inhalation of this form cannot be excluded. The additive is an efficacious source of copper in meeting animal requirements.

The opinion was adopted.[11]

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

Not discussed due to lack of time.

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

Not discussed due to lack of time.

5.10. Rovabio® Spiky (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase) for chickens for fattening, chickens reared for laying, minor poultry species (for fattening and reared for laying) (EFSA-Q-2013-00750)

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 Rovabio® Spiky (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase) as a zootechnical additive for chickens for fattening, chickens reared for laying and minor poultry species (for fattening and reared for laying).

The draft opinion was discussed. The Panel concluded that the additive does not raise a safety concern with regard to the genetically modified production strain and is safe for the target species, consumers and environment. The additive should be considered a potential skin sensitiser and potentially harmful if inhaled. The Panel also concluded that the additive has the potential to be efficacious in the target species.

The opinion was adopted.[12]

5.11. Formaldehyde for pigs and poultry (EFSA-Q-2013-00763)

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 formaldehyde as a technological additive for pigs and poultry.

The draft opinion was discussed. The Panel concluded the proposed use of formaldehyde as a feed additive would not pose a risk to the consumer and the environment. A safe level for all animal species and categories, including all poultry and all pigs, could not be determined and no safe level of exposure of the skin, eyes or the respiratory system to formaldehyde could be identified. The Panel also concluded that the additive has the potential to be effective in reducing bacterial growth in an already contaminated feed at a lowest concentration of about 200 mg/kg complete feed, while the prevention of re-contamination requires considerably higher concentrations.

The opinion was adopted.[13]

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11 http://www.efsa.europa.eu/en/efsajournal/pub/3796.htm
12 http://www.efsa.europa.eu/en/efsajournal/pub/3793.htm
13 http://www.efsa.europa.eu/en/efsajournal/pub/3790.htm

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

Not discussed due to lack of time.

5.13. Toyocerin® (*Bacillus toyonensis* NCIMB 14858T) for chickens for fattening, weaned piglets, pigs for fattening, sows for reproduction, cattle for fattening, calves for rearing and rabbits for fattening (EFSA-Q-2014-00043)

The rapporteur presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety of Toyocerin® (*Bacillus toyonensis* NCIMB 14858^T) as a zootechnical additive for sows for reproduction, piglets, pigs for fattening, cattle for fattening, chickens for fattening, rabbits for fattening, calves for rearing based on the additional data submitted by the applicant.

The draft opinion was discussed. The Panel confirmed the conclusions reached in its previous opinion that *B. toyonensis* NCIMB 14858^T poses a risk for the spread of genes coding for resistance to tetracycline and chloramphenicol, antibiotics of human and veterinary importance, and has the capacity to elaborate functional toxins and thus, to pose a risk to humans exposed to the organism. The Panel also concluded that Toyocerin® has the potential to improve performance of weaned piglets and that its active agent is compatible with decoquinate, diclazuril and robenidine.

The opinion was adopted.[14]

5.14. Selenium-enriched yeast *Saccharomyces cerevisiae* NCYC R645 (SelenoSource AF 2000) for all animal species (EFSA-Q-2014-00090)

The rapporteur presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety for the target animals and users of selenium in the form of organic compounds produced by the selenium-enriched yeast *Saccharomyces cerevisiae* NCYC R645 as a nutritional additive for all species taking into account its earlier opinion, and the supplementary information submitted by the applicant.

The draft opinion was discussed. The Panel concluded that the additive is considered to be a safe source of selenium for all animal species/categories when used up to the total maximum authorised selenium content in complete feed. In the absence of data, the additive should be treated as an irritant to skin and eyes, as a dermal and respiratory sensitiser and as inhalation toxicant.

The opinion was adopted.[15]

5.15. Lenziaren (iron, aqua carbonate hydroxy oxo starch sucrose complex) for cats (EFSA-Q-2014-00298)

The rapporteur presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the efficacy of Lenziaren (iron, aqua carbonate hydroxy oxo starch sucrose complex) as a zootechnical additive for cats based on the additional data submitted by the applicant.

The draft opinion was discussed. The Panel concluded that Lenziaren has the potential to be efficacious in binding intestinal phosphorus at the minimum recommended dose of 0.25 g/cat and day.

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14 http://www.efsa.europa.eu/en/efsajournal/pub/3766.htm
15 http://www.efsa.europa.eu/en/efsajournal/pub/3797.htm

The opinion was adopted.[16]

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-2014-00457	Perlite for ruminants and poultry
EFSA-Q-2014-00458	Lignosulphonate of magnesium (CaimaBond) for all animal species
EFSA-Q-2014-00460	6-Palmityl-L-ascorbic acid for all animal species and categories
EFSA-Q-2014-00375	Levucell SC 20, Levucell SC10 ME and/or Titan (*Saccharomyces cerevisiae* CNCM I-1077) for dairy cows for milk production and cattle for fattening
EFSA-Q-2014-00459	Vermiculite for pigs, poltry, sheep, goats, rabbits and horses
EFSA-Q-2014-00455	Lecithins for all animal species
EFSA-Q-2014-00464	Lipidol Lecithin (Lipidol)
EFSA-Q-2014-00447	Ronozyme® WX (CT)/Ronozyme® WX (L) (endo-1,4-beta-xylanase) for chickens for fattening, turkeys for fattening, all minor poultry species for fattening, piglets (weaned), pigs for fattening
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.
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)

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
1	EFSA-Q-2014-00224	Biomin® C3 (*Bifidobacterium animalis* ssp. *animalis* (16284), *Lactobacillus salivarius* ssp. *salivarius* (16351) and *Enterococcus faecium* (21913)) for chickens for fattening and chickens reared for laying	21/05/2014
2	EFSA-Q-2014-00234	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)	23/05/2014

[16] http://www.efsa.europa.eu/en/efsajournal/pub/3791.htm

3	EFSA-Q-2014-00091	Bactocell PA or Fermaid PA for pigs for fattening and chickens for fattening	26/05/2014
4	EFSA-Q-2014-00290	Deccox® 60G (Decoquinate) for chickens for fattening	28/05/2014
5	EFSA-Q-2013-00972	Bacillus Subtilis PB6 (*Bacillus subtilis* ATCC PTA-6737) for laying hens and other minor laying poultry birds	04/06/2014
6	EFSA-Q-2014-00288	Semi-refined carrageenan for dogs and cats	04/06/2014
7	EFSA-Q-2014-00291	Natugrain® TS, Natugrain® TS L (endo-1,4-beta-xylanase, endo-1,4-beta-glucanase) for chickens for fattening	05/06/2014
8	EFSA-Q-2014-00299	L-valine (minimum: 98% L-valine, production strain VA-05 (NITE BP-01755) for all animal species	12/06/2014
9	EFSA-Q-2013-00752	ELANCOBAN® G200 (monensin sodium) for chickens for fattening, chickens reared for laying, turkeys	13/06/2014
10	EFSA-Q-2014-00156	Bentonite (UltraSorb Binder) for piglets, pigs, pigs for fattening, sows for reproduction, chickens for fattening, chickens reared for laying, laying hens, ducks for fattening, ducks for breeding, turkeys for breeding purposes, turkeys for fattening, calves for fattening, calves for rearing, cows for breeding, dairy cows for milk production, cattle for fattening, dairy sheep (for milk production), ewes for breeding, dairy goats (for milk production),goats for breeding, lambs for fattening, lambs for rearing, goats, kids for fattening, kids for rearing, horses	20/06/2014
11	EFSA-Q-2014-00029	Levucell SC 20, Levucell SC10 (ME) / Titan (*Saccharomyces cerevisiae* CNCM I-1077)	23/06/2014

These applications were assigned to the working groups on Microorganisms (#1-3, 5 & 11), Coccidiostats (#4 & 9), Technological additives (#6), Enzymes (#7), Amino acids (#8) and Mycotoxin detoxifying agents (#10).

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

a. The Head of the Repro department presented the Matrix project regarding the electronic management of the applications received by EFSA for risk assessment in the area of regulated products.

b. A member of the EXO unit presented the new document management system that will be implemented in EFSA.

c. A member of the WG on Vitamins made a short presentation to introduce the draft opinion on the safety of *Solanum glaucophyllum* leaves, that will be discussed in the next plenary.

8. Other scientific topics for information and/or discussion

- Not discussed

9. Any other business

- The Panel agreed on the dates for the plenary meetings for 2015: 27-29 January, 10-12 March, 28-30 April, 9-11 June, 7-9 July, 8-10 September, 20-22 October and 1-3 December.