European Food Safety Authority

FEED UNIT

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

Minutes of the 102nd Plenary Meeting

Held on 4-6 March 2014, Parma

(Agreed on 8 April 2014)

Participants

- **Panel Members**

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

- **Hearing Experts**

  N/A

- **European Commission**

  N/A

- **EFSA**

  - **FEED Unit:** Claudia Roncancio-Peña, Jaume Galobart, Maria Vittoria Vettori, Rosella Brozzi, Gloria López-Gálvez and Paola Manini.
  - **Legal and Regulatory Affairs Unit:** Dirk Detken[3]

- **Observers**

  N/A

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Giovanna Martelli and Johannes Westendorf.

2. Adoption of agenda

The agenda was adopted after the deletion of the item “Update of Technical Guidance on the assessment of the toxigenic potential of *Bacillus* species used in animal nutrition (EFSA-Q-2013-00303)”.

1 Present only on 5-6 March.
2 Present only on 4-5 March.
3 Present only on 3 March for Item 7.

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 (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 interest was declared.

4. Agreement of the minutes of the 101st Plenary meeting held on 28-30 January 2014

The minutes of the 101st Plenary meeting were reviewed and agreed.[6]

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

5.1. Chemically defined flavourings from Chemical Group 34 - Amino acids for all animal species and categories (EFSA-Q-2010-01170)

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 Chemically defined flavourings from Chemical Group 34 - amino acids as sensory additives for all animal species and categories.

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.

5.2. Chemically defined flavourings – disodium 5'-ribonucleotides, disodium 5'-guanylate and disodium 5'-inosinate for all animal species (EFSA-Q-2010-01285)

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 disodium 5'-ribonucleotides, disodium 5'-guanylate and disodium 5'-inosinate as sensory additives for all animal species.

The draft opinion was discussed. The Panel concluded that disodium 5'-guanylate and disodium 5'-inosinate and their mixture are considered to be safe for the target animals and the consumer. However, considering the lack of information on the production process, these conclusions apply only to the compounds 'per se' and their extrapolation to any feed additive containing these compounds is not possible. It would be prudent to regard the compounds as potentially hazardous to workers by skin or inhalation exposure. The Panel also concluded that these compounds are safe for the environment and that no further demonstration of efficacy is required.

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/independencerules.pdf
6 http://www.efsa.europa.eu/en/events/event/140128a-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/3606.htm

5.3. Astaxanthin for salmon and trout, other fish, crustaceans, ornamental fish, ornamental birds (EFSA-Q-2011-01070)

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 astaxanthin as a sensory additive for salmon and trout, other fish, crustaceans, ornamental fish, ornamental birds.

The draft opinion was discussed. The Panel concluded that synthetic astaxanthin is safe for salmonids, other fish, ornamental fish and crustaceans, but could not conclude on the safety for ornamental birds. The use of astaxanthin up to the maximum permitted dietary level for salmon and trout is of no concern for the safety of the consumer. The Panel considered it prudent to regard astaxanthin-containing additives as being potentially hazardous by inhalation and by exposure to skin and eyes. The use of synthetic ATX is unlikely to pose a significant additional risk to the environment compared with natural astaxanthin. The Panel also concluded that astaxanthin is efficacious in colouring salmonids, other fish, crustaceans and ornamental fish, but no conclusion could be made on its efficacy for ornamental birds.

The opinion was adopted.

5.4. Astaxanthin (Carophyll Pink) for salmonids and ornamental fish (EFSA-Q-2011-01071)

The Chair 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 synthetic astaxanthin as a sensory additive for salmonids and ornamental fish.

The draft opinion was discussed. The Panel concluded that synthetic astaxanthin is safe for salmonids and ornamental fish. The use of astaxanthin up to the maximum permitted dietary level for salmon and trout is of no concern for the safety of the consumer. The additive is unlikely to be irritant to skin/eyes or a skin sensitiser, and risk of inhalation toxicity is minimal for the formulation tested. The use of synthetic ATX is unlikely to pose a significant additional risk to the environment compared with natural astaxanthin. The Panel also concluded that astaxanthin is efficacious in colouring salmonids and ornamental fish.

The opinion was adopted.

5.5. *Pediococcus pentosaceus* (NCIMB 30068) for all animal species (EFSA-Q-2012-00081)

The Chair 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 *Pediococcus pentosaceus* (NCIMB 30068) as a technological additive for all animal species.

The draft opinion was discussed. The strain carries an uncharacterised resistance to tetracycline, and therefore is not safe for the target species and consumer. The additive should be regarded as a skin and eye irritant and a potential skin and respiratory sensitiser. The Panel cannot conclude on its safety for the environment. The Panel also stated that there was insufficient evidence to conclude on its efficacy.

The opinion was adopted.[9]

5.6. *Lactobacillus paracasei* (NCIMB 30151) for all animal species (EFSA-Q-2012-00082)

The Chair 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 *Lactobacillus paracasei* (NCIMB 30151) as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that the use of the strain as a silage additive is safe for the target species, consumers and the environment. The additive should be regarded as a skin and eye irritant and a potential skin and respiratory sensitiser. The Panel also concluded that the additive has the potential to improve the production of silage.

The opinion was adopted.[10]

5.7. *Lactobacillus plantarum* (DSMZ 16627) for all animal species (EFSA-Q-2012-00083)

The Chair 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 *Lactobacillus plantarum* (DSMZ 16627) as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that the use of the strain as a silage additive is safe for the target species, consumers and the environment. The additive should be regarded as a skin and eye irritant and a potential skin and respiratory sensitiser. The Panel also concluded that the additive has the potential to improve the production of silage.

The opinion was adopted.[11]

5.8. *Pediococcus acidilactici* (NCIMB 30005) for all animal species (EFSA-Q-2012-00084)

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 *Pediococcus acidilactici* (NCIMB 30005) as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that the use of the strain as a silage additive is safe for the target species, consumers and the environment. The additive should be regarded as a skin and eye irritant and a potential skin and respiratory sensitiser. The Panel also concluded that the additive has the potential to improve the production of silage.

The opinion was adopted.[12]

9 http://www.efsa.europa.eu/en/efsajournal/pub/3609.htm
10 http://www.efsa.europa.eu/en/efsajournal/pub/3611.htm
11 http://www.efsa.europa.eu/en/efsajournal/pub/3612.htm
12 http://www.efsa.europa.eu/en/efsajournal/pub/3613.htm

5.9. *Pediococcus pentosaceus* (NCIMB 30044) for all animal species (EFSA-Q-2012-00087)

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 *Pediococcus pentosaceus* (NCIMB 30044) as a technological additive for all animal species.

The draft opinion was discussed. The strain carries an uncharacterised resistance to tetracycline, and therefore is not safe for the target species and consumer. The additive should be regarded as a skin and eye irritant and a potential skin and respiratory sensitiser. The Panel cannot conclude on its safety for the environment. The Panel also concluded that the additive has the potential to improve the production of silage.

The opinion was adopted.[13]

5.10. Oralin® (*Enterococcus faecium* DSM 10663/NCIMB 10415) for cats (EFSA-Q-2012-00245)

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 Oralin® (*Enterococcus faecium* DSM 10663/NCIMB 10415) as a zootechnical additive for cats.

The draft opinion was discussed. The Panel concluded that the additive is safe for cats and the environment and that concerns for users are limited to the potential of being a respiratory sensitiser. The Panel also concluded that the significant but limited improvement in faecal scores seen in three studies is questionable in terms of biological relevance.

The opinion was adopted.[14]

5.11. Ferrous sulphate monohydrate for all animal species (EFSA-Q-2012-00493)

The Chair 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 Ferrous sulphate monohydrate as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that ferrous sulphate monohydrate is safe when supplied up to the maximum iron content per kilogram complete feedingstuffs of 450 mg for bovines and poultry, 500 mg for ovines, 600 mg for pets, and 750 mg for other species/categories, except horses and fish; for piglets up to one week before weaning a daily maximum dose of 250 mg Fe is considered safe. Because of insufficient data, the FEEDAP Panel is not in a position to derive a maximum safe iron concentration in feed for horses or fish; as a provisional measure, the current value for other animal species (750 mg/kg) could be maintained. The additive is safe for consumers and the environment but it is a hazard for users. The Panel also concluded that ferrous sulphate monohydrate is an effective source of iron for all animal species. The FEEDAP Panel recommended a reduction of the currently authorised maximum iron content in complete feed for bovines, poultry and pets.

The opinion was adopted.[15]

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13 http://www.efsa.europa.eu/en/efsajournal/pub/3610.htm
14 http://www.efsa.europa.eu/en/efsajournal/pub/3602.htm
15 http://www.efsa.europa.eu/en/efsajournal/pub/3607.htm

5.12. Chemically defined flavourings from Chemical Group 13 - Furanones and tetrahydrofurfuryl derivates: 5-ethyl-3-hydroxy-4-methylfuran-2(5H)-one and 3-hydroxy-4,5-dimethylfuran-2(5H)-one for all animal species (EFSA-Q-2012-00632)

The rapporteur presented the question and draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of 5-ethyl-3-hydroxy-4-methylfuran-2(5H)-one and 3-hydroxy-4,5-dimethylfuran-2(5H)-one as sensory additives for all animal species.

The draft opinion was discussed. The Panel concluded that the additives are safe for the target species at concentrations of 0.05 mg/kg feed for poultry and pigs and 0.08 mg/kg feed for cattle, salmonids and non-food-producing animals. At these levels, they are considered safe also for consumers and the environment. These compounds should be treated as irritants to skin, eyes and the respiratory tract and as skin sensitisers. The Panel also concluded that since these compounds are used in food as flavourings, and their function in feed is essentially the same as that in food, no further demonstration of efficacy is necessary.

The opinion was adopted.[16]

5.13. Potential modification of the currently authorised maximum zinc content in feed (EFSA-Q-2012-00966)

The rapporteur presented the question. EFSA has been requested to deliver an opinion on the potential reduction of the currently authorised maximum zinc content in complete feed considering safety for animals, consumers and the environment.

The draft opinion was discussed. The Panel identified some issues that required further development in the opinion and asked the WG to provide with an updated draft to the next plenary meeting.

5.14. Miya-Gold® EU (*Clostridium butyricum* FERM-BP 2789) for turkeys for fattening and turkeys reared for breeding to point of lay (EFSA-Q-2013-00594)

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 Miya-Gold® EU (*Clostridium butyricum* FERM-BP 2789) as a zootechnical additive for turkeys for fattening and turkeys reared for breeding to point of lay.

The draft opinion was discussed. The Panel concluded that the new data on the whole genome sequence of *C. butyricum* FERM BP-2789 do not raise issues which would lead to revision of the conclusions on the safety of the product for consumers, users and the environment reached in previous opinions. The additive is considered safe and efficacious for the target species.

The opinion was adopted.[17]

[16] http://www.efsa.europa.eu/en/efsajournal/pub/3608.htm
[17] http://www.efsa.europa.eu/en/efsajournal/pub/3603.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-2014-00091	Bactocell PA or Fermaid PA (*Pediococcus acidilactici* CNCM MA 18/5M) for pigs and chickens for fattening
EFSA-Q-2014-00115	Hemicell® HT and Hemicell® (endo-1,4-beta-mannanase) for piglets (weaned), pigs for fattening, minor porcine species, chickens for fattening, chickens reared for laying, minor poultry species, turkeys reared for breeding, turkeys for fattening

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-2013-00704	Bactocell PA 10 and Bactocell PA 10 ME (*Pediococcus acidilactici* CNCM ME 18/5M) for minor avian and minor porcine species	24/01/2014
2	EFSA-Q-2013-00770	Astaxanthin-rich *Phaffia rhodozyma* KBW 10061 (AJ 14971) (Ajinomoto Phaffia Astaxanthin) for salmon and trout	06/02/2014
3	EFSA-Q-2013-00768	Alpha-Lipoic acid for dogs	07/02/2014
4	EFSA-Q-2012-00955	Riboflavin sodium phosphate for all animal species	11/02/2014
5	EFSA-Q-2013-00767	Monteban® G100 (Granular narasin, equivalent to 100g narasin activity) for chickens for fattening	17/02/2014
6	EFSA-Q-2014-00003	L-Lysine sulphate produced by fermentation with *Escherichia coli* K12 for all animal species	17/02/2014
7	EFSA-Q-2012-00994	Sacox (salinomycin sodium) for chickens reared for laying	24/02/2014

These applications were assigned to the working groups on Microorganisms (#1), Colourings (#2), Technological additives (#3), Vitamins (#4), Coccidiostats (#5 & 7) and amino acids (#6).

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

- The Head of the Legal and Regulatory Affairs of EFSA made a presentation regarding diverging opinions in the framework of Article 30 or Regulation (EC) No 178/2002.
- The Panel were informed on the comments that will be submitted to the NDA Panel in the framework of the consultation on Dietary Reference Values for iodine.

- The Panel was informed on the outcome and recommendations on the External Review Working Group.

8. Other scientific topics for information and/or discussion

- A discussion took place regarding the need to update the requirements for the assessment of additives produced by fermentation. The outcome of the discussion is available in Annex II.
- The Head of Unit and the Vice-Chair of the Panel provided feedback regarding the meeting of the UK's Advisory Committee on Animal Feed (ACAF) they attended.

9. Any other business

- The Panel was informed about an erratum identified in five opinions regarding iodine: EFSA-Q-2003-058 (adopted on 25 January 2005); EFSA-Q-2011-00744, EFSA-Q-2011-00745 and EFSA-Q-2011-00746 (adopted on 29 January 2013); EFSA-Q-2011-00747 (adopted on 14 March 2013). These errata will be corrected in the concerned opinions.
- The Panel was informed about an erratum identified in the opinion on Miya-Gold®S (*Clostridium butyricum*) as feed additive for chickens for fattening (EFSA-Q-2008-303) adopted on 2 April 2009. This erratum will be corrected.

Annex I

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

In the SDoI filled for the present meeting Dr. Baltasar Mayo declared that his laboratory had performed some analysis related to the dossiers "*Pediococcus pentosaceus* (NCIMB 30068) for all animal species (EFSA-Q-2012-00081)*", "Lactobacillus paracasei* (NCIMB 30151) for all animal species (EFSA-Q-2012-00082)", "*Lactobacillus plantarum* (DSMZ 16627) for all animal species (EFSA-Q-2012-00083)", "*Pediococcus acidilactici* (NCIMB 30005) for all animal species (EFSA-Q-2012-00084)" and "*Pediococcus pentosaceus* (NCIMB 30044) for all animal species (EFSA-Q-2012-00087)**.** In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above were deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when those items of the meeting (5.5, 5.6, 5.7, 5.8 and 5.9) are discussed, voted on or in anyway processed by that concerned scientific group.

Annex II

Update on the requirements for the assessment of additives produced by fermentation

The FEEDAP Panel notes that Regulation (EC) No 429/2008 and the corresponding guidance documents of the FEEDAP Panel[18] do not specifically request the provision of data on antimicrobial resistance of the production strain and the potential for production of toxins for additives produced by fermentation.

Since this information is highly relevant, especially when products are not highly purified, the Panel would like to clarify that the requirements described below apply to substances produced by fermentation/cultivation, without prejudice of the requirements already established in Regulation (EC) No 429/2008.

Depending on the manufacturing/production process, two types of product are considered:

1. **Highly purified products**, obtained from high purification process (e.g., crystallization, ultrafiltration, membrane dialysis, chromatography)
2. **Other fermentation products**

The following requirements apply to all products:

- Absence of viable cells of the production strain in the additive or in the fermentation product used to formulate the additive.
- Microbiological contamination and, depending on the fermentation media and excipients, chemical contamination (mycotoxins, heavy metals, arsenic).
- For fermentation products produced by genetically modified microorganisms (GMMs), identification and quantification of recombinant DNA (including antibiotic resistance genes, if relevant) in the final product. The requirements of the GMM guidance[19] apply.
- The use of any antimicrobial compounds during the production process should be declared and the presence of any residues in the final product investigated.

The following requirements apply to "other fermentation products":

- The extent to which spent growth medium is incorporated into the final product.
- Absence of substances with antimicrobial activity relevant to the use of antibiotics in humans or animals:
  - ✓ For those strains known to be capable of producing antimicrobials, the antimicrobial activity in the final product should be investigated by appropriate sensitive methods.
  - ✓ For strains for which little is known regarding the potential production of antimicrobial substances, the presence of antimicrobial activity in the fermentation/final product should be investigated. To this end, the methodologies proposed by the FEEDAP Panel[20] and JECFA[21] are considered valid for screening purposes.

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18 http://www.efsa.europa.eu/en/feedapguidance/feedaptechguidance.htm

19 Guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use http://www.efsa.europa.eu/en/efsajournal/pub/2193.htm

20 Technical Guidance: Microbial studies http://www.efsa.europa.eu/en/efsajournal/doc/836.pdf

- Depending on the nature of the production organism, absence of toxins and toxic metabolites applies
- The production strain should be tested for resistance to the antibiotics listed "Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance".[22]

If atypical antibiotic resistance is detected, it should be demonstrated that DNA from the production strain is not present in the final product. This can be done by PCR targeting known DNA sequences coding for the resistance or other sequences specific to the production strain. In this case, the specificity of the targeted sequence should be demonstrated.[23] If DNA is detected in the final product, then the genetic basis of the resistance should be assessed according to the "Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance".

[21] JECFA Combined compendium of food additive specifications (1956-2005) Volume 4. Analytical methods, test procedures and laboratory solutions used by and referenced in the food additive specifications ftp://ftp.fao.org/docrep/fao/009/a0691e/a0691e.pdf (pag. 122)

[22] Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance http://www.efsa.europa.eu/en/efsajournal/pub/2740.htm

[23] Guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use http://www.efsa.europa.eu/en/efsajournal/pub/2193.htm