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

Minutes of the 97th Plenary Meeting

Held on 9-11 July 2013, Parma

(Agreed on 10 September 2013)

Participants

- **Panel Members**

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

- **Hearing Experts**

  Lieve Herman (for items 5.5, 5.6 and 5.8)[3]

- **European Commission**

  N/A

- **EFSA**

  - **FEED Unit:** Claudia Roncancio-Peña, Jaume Galobart, Montserrat Anguita, Gloria López-Gálvez, Lucilla Gregoretti, Jordi Tarrés-Call, Maria Vittoria Vettori, Nicola Jane Reynolds and Cecilia Lloyd.

- **Observers**

  N/A

1. Welcome and apologies for absence

The Chair welcomed the participants, especially Lucio Guido Costa who has recently joined the Panel.

Apologies were received from Johannes Westendorf.

The Chair informed that Alex Bach has resigned as a member of the Panel.

2. Adoption of agenda

The agenda was adopted after the deletion of the items “L-tryptophan technically pure for all animal species (EFSA-Q-2011-00948)”, “Ferrous sulphate monohydrate for all animal

[1] Present only on 9 and 10 July.
[2] Present only on 9 and 10 July.
[3] Present only on 9 July.

species (EFSA-Q-2012-00493)", "Ferrous sulphate heptahydrate for all animal species (EFSA-Q-2012-00494)" and "Ferrous carbonate for all animal species (EFSA-Q-2012-00495)".

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 96th Plenary meeting held on 18-20 June 2013

The minutes of the 96th Plenary meeting were reviewed and agreed.[6]

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

5.1. Endofeed® DC (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase) for chickens for fattening, laying hens, pigs for fattening, minor avian and porcine species (EFSA-Q-2009-00585)

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 Endofeed® DC (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase) as a zootechnical additive for chickens for fattening, laying hens, pigs for fattening, minor poultry and porcine species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species. However, in the absence of adequate studies, the Panel cannot conclude on the safety of Endofeed® DC for the consumer. In the absence of data, the additive should be considered as a potential skin/eye irritant and a skin/respiratory sensitizer. It is considered safe for the environment. The Panel also concluded that the additive has the potential to be efficacious in the target species.

The opinion was adopted.[8]

5.2. Chemically defined flavourings from Flavouring Group 29 - Thiazoles, thiophene, thiazoline and thienyl derivatives for all animal species and categories (EFSA-Q-2010-01180)

The Chair 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 the chemically defined flavourings from Chemical Group 29 as sensory additives for all animal species. The current opinion concerns only 3-acetyl-2,5-dimethylthiophene.

The draft opinion was already partially discussed during the last plenary meeting. The Panel concluded that 3-acetyl-2,5-dimethylthiophene is mutagenic and therefore is

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/130618-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/3322.htm

considered not safe for the target species, the consumer of animal products and the user. The Panel also concluded that 3-acetyl-2,5-dimethylthiophene at 0.05 mg/kg feed for all species does not pose a risk for the environment and that since this compound is used in food as flavouring, and its function in feed is essentially the same as that in food, no further demonstration of efficacy is necessary.

The opinion was adopted.[9]

5.3. Rovabio® Excel (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase) for chickens for fattening, laying hens, turkeys for fattening, piglets (weaned), pigs for fattening, ducks, guinea fowls, quails, geese, pheasants, pigeons (EFSA-Q-2010-01287)

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 the Rovabio® Excel (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase) as a zootechnical additive for chickens for fattening, laying hens, turkeys for fattening, piglets (weaned), pigs for fattening, ducks, guinea fowls, quails, geese, pheasants, pigeons.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumers and the environment. Concerns for users are limited to skin/respiratory sensitisation. The additive has the potential to be efficacious in the target species at the corresponding recommended dose. The Panel made a recommendation to change the specifications of the product.

The opinion was adopted.[10]

5.4. Quinoline Yellow for non food-producing animals (EFSA-Q-2010-01523)

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 Quinoline Yellow as a sensory additive (colouring agent) for non food-producing animals.

The draft opinion was discussed. The Panel concluded that Quinoline Yellow is safe for the target species at a dose of 25 mg/kg complete feed. The additive should be considered a skin/eye irritant, a skin sensitiser and hazardous by inhalation. In the absence of any information, the efficacy of Quinoline Yellow, with respect to the dose and the nature of the feedingstuffs and their processing, could not be assessed.

The opinion was adopted.[11]

5.5. L-tryptophan technically pure for all animal species (EFSA-Q-2011-00947)

The Chairs of the WGs presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of L-tryptophan technically pure as a nutritional additive for all animal species. L-tryptophan is produced by a genetically modified strain of *Escherichia coli*.

The draft opinion was partially discussed. However, due to lack of time, the opinion will be sent to the next plenary for possible adoption.

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9 http://www.efsa.europa.eu/en/efsajournal/pub/3323.htm
10 http://www.efsa.europa.eu/en/efsajournal/pub/3321.htm
11 http://www.efsa.europa.eu/en/efsajournal/pub/3320.htm

5.6. Concentrated liquid L-lysine (base) for all animal species (EFSA-Q-2011-00992), concentrated liquid L-lysine-monohydrochloride for all animal species (EFSA-Q-2011-00993) and L-lysine-monohydrochloride technically pure for all animal species (EFSA-Q-2011-00994)

The rapporteurs presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of L-lysine in three forms (concentrated liquid L-lysine (base), concentrated liquid L-lysine-monohydrochloride and and L-lysine-monohydrochloride technically pure) as nutritional additives for all animal species.

The draft opinion was discussed. The Panel identified some issues that required further discussion and decided to continue the discussion during the next plenary meeting.

5.7. Biostrong® 510 (preparation of essential oil of thyme and star anise) for chickens and minor avian species for fattening and rearing to point of lay (EFSA-Q-2011-01152)

Not discussed due to lack of time.

5.8. L-threonine technically pure for all animal species (EFSA-Q-2012-00114)

The Chairs of the WGs presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of L-threonine technically pure as a nutritional additive for all animal species. L-threonine is produced by a genetically modified strain of *Escherichia coli*.

The draft opinion was discussed. The Panel concluded that the final product does not raise concerns with regard to the genetic modification. The additive is considered safe for the target species, consumers, users and the environment, and is also considered an efficacious source of L-threonine for all animal species.

The opinion was adopted.[12]

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

Not discussed due to lack of time.

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

Not discussed due to lack of time.

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

Not discussed due to lack of time.

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

Not discussed due to lack of time.

[12] http://www.efsa.europa.eu/en/efsajournal/pub/3319.htm

5.13. Manganese amino acid chelate, hydrate for all animal species (EFSA-Q-2012-00436)

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 manganese amino acid chelate, hydrate as a nutritional additive for all animal species.

The draft opinion was partially discussed in the last plenary meeting. The Panel concluded that manganese amino acid chelate, hydrate is safe for the target species, consumers and the environment provided that the currently authorised maximum contents of manganese in feed are respected. The additive should be considered as potential skin/eye irritant and a skin/respiratory sensitiser; its handing is a possible hazard to the respiratory tract and the health of users. The Panel also concluded that manganese amino acid chelate, hydrate is an effective source of manganese for all animal species.

The opinion was adopted.[13]

5.14. Manganous oxide for all animal species (EFSA-Q-2012-00439)

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 manganese oxide as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that manganese oxide is safe for the target species, consumers and the environment provided that the currently authorised maximum contents of manganese in feed are respected. The additive should be considered as potential skin/eye irritant, a skin sensitiser and hazardours by inhalation. The Panel also concluded that manganese oxide is an effective source of manganese for all animal species.

The opinion was adopted.[14]

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-2013-00612	Citric acid for all animal species

[13] http://www.efsa.europa.eu/en/efsajournal/pub/3324.htm
[14] http://www.efsa.europa.eu/en/efsajournal/pub/3325.htm

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-2013-00321	S-Adenosyl-L-Methionine Disulfate p-Toluenesulfonate for cats and dogs	28/06/2013

This application was assigned to the working groups on Technological additives.

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

- The Panel acknowledges the publication of the Statement on Allura Red AC and other sulphonated mono azo dyes authorised as food and feed additives, which was adopted by the ANS Panel on 15 May 2013.
- The Panel was informed that the public consultation on the draft "Guidance on the assessment of the toxigenic potential of *Bacillus* species used in animal nutrition" has been extended until 30 September.
- The Panel was also informed of the public consultation on a EFSA's NDA Panel draft scientific opinion on dietary reference values for vitamin C.

8. Other scientific topics for information and/or discussion

Not discussed

9. Any other business

- The plenary meeting in November (5-7) has been cancelled.
- The following dates for the plenary meetings in 2014 were agreed: 28-30 January, 4-6 March, 8-10 April, 20-22 May, 1-3 July, 9-11 September, 28-30 October and 9-11 December.