MINUTES OF THE 64TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (FEEDAP)

(PARMA, 9-10 DECEMBER 2009)

(AGREED ON 2 FEBRUARY 2010)

PARTICIPANTS

Panel Members

Gabriele Aquilina, Georges Bories, Paul Brantom, Francesca Caloni, Andrew Chesson, Pier Sandro Cocconcelli, Noël Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle (1st day), Nils-Gunnar Ilbäck, Reinhard Kroker, Lubomir Leng, Sven Lindgren, Anne-Katrine Lundebye Haldorsen, Alberto Mantovani, Miklós Mézes, Derek Renshaw and Maria Saarela (1st day).

Apologies

Joop de Knecht, Ingrid Halle (2nd day) and Maria Saarela (2nd day).

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Gloria López-Gálvez, Rosella Brozzi, Montserrat Anguita, Lucilla Gregoretti (scientific staff), Giulia Frattini (administrative staff).

European Commission

Marta Ponghellini, Marina Marini (DG SANCO), Christoph von Holst, Giuseppe Simone (DG JRC)

---

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 64th Plenary meeting of the FEEDAP Panel. The Chair also welcomed two new staff members that have joined the FEEDAP Unit, Paola Manini and Nicola Jane Reynolds.

Members not able to attend the meeting had sent their apologies (see under participants).

2. ADOPTION OF THE AGENDA

The agenda was adopted after the deletion of the item on "Assessment of herbs, essential oils and other plant products as additives for use in animal nutrition (EFSA-Q-2004-064)".

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and Specific Declaration of interest (SDoI) 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 beginning of this

meeting.

4. ADOPTION OF THE DRAFT MINUTES OF THE 63RD PLENARY MEETING

The minutes of the 63rd Plenary meeting of the Scientific Panel held on 11-12 November 2009 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Mintrex® Mn (manganese chelate of hydroxy analogue of methionine) for all animal species (EFSA-Q-2009-00630)**

  The Rapporteur from the Working Group (WG) presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety for consumers and for the target animals of the product manganese chelate of hydroxyl analogue of methionine when used as a feed additive for all animal species. In an opinion adopted in 2008,[2] the FEEDAP Panel could only conclude on the safety for chickens for fattening. It was not possible to fully conclude on the safety for the consumer due to the limited data and the possible health consequences caused by an additional exposure to Mn, as expressed previously also by the Scientific Committee on Food. In a second opinion adopted in 2009,[3] the FEEDAP Panel concluded that the use of Mintrex®Mn as a feed additive for chickens for fattening is unlikely to present a safety concern to consumers. The applicant has provided new data on the safety of the product for all species and for the consumer.

  The draft opinion was reviewed. Based on the new data provided, the FEEDAP Panel concluded that the use of Mintrex®Mn up to the maximum authorised total manganese content in feed is safe for all species and for consumers.

  The opinion was adopted.[4]

- **L-isoleucine for all animal species (EFSA-Q-2009-00456)**

  The Rapporteur from the WG presented the question and the draft opinion. This question refers to an application for the authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking the authorisation of this product as a nutritional additive for all animal species. L-isoleucine is produced by the genetically modified micro-organism *Escherichia coli* (K-12 3149 – FERM ABP-10641). The safety aspects of the genetic modification have been assessed by the GMO Panel.[5]

  The draft opinion was already discussed in the previous Plenary meeting. The Panel concluded that the product L-isoleucine is a source of available isoleucine and is safe for all animal species, consumers and the environment when used as a feed additive. No major risks are expected for the users of the products.

  The opinion was adopted.[6]

[1] http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap091111m.pdf?ssbinary=true
[2] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178706515725.htm
[3] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902905600.htm
[4] http://www.efsa.europa.eu/en/scdocs/scdoc/1424.htm
[5] Adopted by the GMO Panel on 2 December 2009
[6] http://www.efsa.europa.eu/en/scdocs/scdoc/1425.htm

- **Calsporin® (*Bacillus subtilis*) for piglets (EFSA-Q-2009-00533)**

  The Rapporteur from the WG presented the question and the draft opinion. This question refers to an application for the authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking the authorisation of this product as a zootechnical additive for piglets.

  The draft opinion was already discussed during the October's Plenary meeting. The active agent (*Bacillus subtilis*) met the requirements for the QPS approach for safety assessment and is therefore considered safe for the target species, the consumer and the environment. The Panel also considered that the product is effective in piglets at the dose proposed by the applicant.

  The opinion was adopted.[7]

- **Natuphos® (3-phytase) for minor avian species (quails, pheasants, partridges, guinea fowl, geese, pigeons, ostriches, peacocks, flamingos) and ornamental birds (EFSA-Q-2009-00603)**

  The Chair of the WG presented the question and the draft opinion. This question refers to an application for the authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking the authorisation of this product as a zootechnical additive for minor avian species and ornamental birds.

  The draft opinion was discussed. The safety of this product for the consumer, user and the environment were already established in previous opinions. The safety and the efficacy of this enzyme preparation have been demonstrated in the relevant major species. The Panel considered that given the wide margin of safety in the major species, the product is safe for the minor poultry species and ornamental birds. Similarly, given the established mode of action and considering an efficacy trial provided in geese, the Panel concluded that the product is efficacious at the dose recommended by the applicant.

  The opinion was adopted.[8]

- **Carotenoid-rich bacterium *Paracoccus carotinifaciens* (Panaferd-AX) for salmon and trout (EFSA-Q-2009-00629)**

  The Rapporteur from the WG presented the question and the draft opinion. This question refers to an application for the modification of the terms of authorisation under Article 13(3) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation to widen the ranges for adonirubin (from 10-15 to 7-15 g/kg) and canthaxanthin (from 3-5 to 1-5 g/kg), while maintaining the astaxanthin specification (20-23 g/kg product) in the product.

  The draft opinion was discussed. The FEEDAP Panel concluded that the modification proposed would, in principle, not affect the safety and efficacy of the product. The data provided by the applicant does not support in full the proposed modifications. However, reviewing the carotenoid composition of the relevant data, it indicated compliance with ranges of 2-5 g canthaxanthin/kg and 9-15 g adonirubin/kg product.

  The opinion was adopted.[9]

[7] http://www.efsa.europa.eu/en/scdocs/scdoc/1426.htm
[8] http://www.efsa.europa.eu/en/scdocs/scdoc/1427.htm
[9] http://www.efsa.europa.eu/en/scdocs/scdoc/1428.htm

- **Guidance for the preparation of dossiers by categories of feed additives. Sensory additives (EFSA-Q-2009-00832)**

  Following the decision taken in the last Plenary meeting, the WG on Guidance made a revision on the chapter "Tolerance for the target species" to amend a miscalculation detected in this section. The Rapporteur of the WG presented the modifications proposed, which were agreed upon by the Panel. The modified version of the guidance will replace the previous version on the web.[10]

5.2. Discussion of the following scientific opinions

- **Quantum™ (6-phytase) for laying hens (EFSA-Q-2009-00804)**

  The Rapporteur from the WG presented the question and the draft opinion. This question refers to an application for the modification of the terms of authorisation under Article 13(3) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation for a modification of the minimum recommended dose from 2000 FTU/kg to 250 FTU/kg.

  The draft opinion was discussed. The opinion will be presented for adoption once the comments from the Member States are received and considered by the WG.

6. PROGRESS REPORT ON ONGOING WORK

The Secretariat informed the Panel that the report on "Review of mycotoxin-detoxifying agents used as feed additives: mode of action, efficacy and feed/food safety" under Article 36 of Regulation (EC) No 178/2002 has been published on the EFSA website.[11] The Panel was also updated on the status of a second call on "Bibliographic review on the potential of micro-organisms, microbial products and enzymes to induce respiratory sensitisation".

7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

Not discussed

8. NEW REQUESTS TO EFSA

8.1. 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 are currently being checked for completeness:

Additive	EFSA-Q-Number
Coxidin (Monensin sodium). Coccidiostat for chickens for fattening and turkeys.	EFSA-Q-2009-00915
Fresta® F (Carvone). Zootechnical additives for weaned piglets.	EFSA-Q-2009-00939
Astaxanthin. Sensory additive for salmon and trout, ornamental fish and birds, crustaceans and other fish.	EFSA-Q-2009-00947
Cassia gum. Technological additive cats and dogs.	EFSA-Q-2009-00948

[10] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902967516.htm

[11] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211903082495.htm

8.2. Valid applications under Regulation (EC) No 1831/2003 since the previous meeting

Applications considered valid for the start of the assessment:

Additive	EFSA-Q-Number	Valid on
Biosprint (*Saccharomyces cerevisiae*). Zootechnical additives for horses	EFSA-Q-2009-00753	11 Nov 2009
Ronozyme® NP (6-phytase). Zootechnical additive for sows	EFSA-Q-2009-00536	30 Nov 2009
Quantum™ (6-Phytase). Zootechnical additive for laying hens.	EFSA-Q-2009-00804	01 Dec 2009

These applications were assigned to the respective working groups.

9. GENERAL INFORMATION FROM EFSA

- Comments to the CEF Panel "Guidance on the data required for the risk assessment of flavourings"[12] were collected and will be transmitted to the CEF Unit in the context of the public consultation.
- Training on the use of webconference was given to the Panel members.

10. MISCELLANEOUS

- The dates for the Plenary meetings for 2010 were reviewed. 2-4 February, 10-11 March, 7-8 April, 25-27 May, 22-23 June, 13-15 July, 7-9 September, 5-7 October, 9-11 November and 7-9 December.
- A discussion took place on a draft document describing the roles of Chairs of working groups and Rapporteurs.
- Ms. Marina Marini, from the European Commission presented a summary of the regulatory follow up to the opinions adopted by the FEEDAP Panel from June-November 2009.

[12] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902971427.htm