MINUTES OF THE 80TH PLENARY MEETING

OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (FEEDAP)

(PARMA, 11-13 OCTOBER 2011)

(AGREED ON 15 NOVEMBER 2011)

PARTICIPANTS

Panel Members
Gabriele Aquilina, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht (2nd and 3rd days), Noël Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle, Christer Hogstrand (2nd and 3rd days), Reinhard Kroker, Lubomir Leng, Anne-Katrine Lundebye Haldorsen (1st and 2nd days), Secundino López Puente, Alberto Mantovani (1st and 2nd days), Giovanna Martelli (2nd and 3rd days), Miklós Mézes, Derek Renshaw, Maria Saarela, Kristen Sejrsen and Johannes Westendorf.

Apologies
Joop de Knecht (1st day), Christer Hogstrand (1st day), Anne-Katrine Lundebye Haldorsen (3rd day), Alberto Mantovani (3rd day), Giovanna Martelli (1st day).

EFSA
Claudia Roncancio-Peña, Jaume Galobart, Matteo Lorenzo Innocenti, Irene Bustos Sepúlveda, Gloria López-Gálvez, Paola Manini, Jordi Tarrés-Call and Nicola Jane Reynolds.

European Commission
Marta Ponghellini (DG SANCO) and Christoph von Holst (DG JRC) (2nd and 3rd days).

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 80th Plenary meeting of the FEEDAP Panel.

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

2. ADOPTION OF THE AGENDA

The agenda was adopted after the removal of the item on Actisaf® Sc 47 for rabbits (EFSA-Q-2010-00936).

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and the 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 79TH PLENARY MEETING

The minutes of the 79th Plenary meeting of the Panel held on 6-8 September 2011 were reviewed and agreed.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **SBS (Sodium bisulphate) for all species (preservative and silage additive); pets and other non food-producing animals (non-food fur animals) as acidity regulator and pets as flavouring (EFSA-Q-2009-00868)**

  The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and for the authorisation of a new use under Article 4 of Regulation (EC) No 1831/2003 of the product sodium bisulphate (SBS) for all animal species as a preservative and a silage additive, for pets and other non food-producing animals as an acidity regulator and for pets as flavouring substance.

  The draft opinion was discussed. The FEEDAP Panel concluded that there is no evidence of the safety of SBS as a preservative for all animal species at the maximum recommended concentration (1%). The Panel also concluded that the product is safe for pets and non food-producing animals when used at a level up to 0.5% and for all species when used as silage additive up to a level of 0.8%. The additive is considered safe for the consumers and the environment, it is an irritant to skin, eye and respiratory tract, and it should be considered as a potential skin sensitizer. SBS is considered efficacious as a preservative for all animal species, as an acidity regulator in feed for pets and other non food-producing animals and as a flavour for pets. However, it is not efficacious as a silage additive at the concentrations tested (0.4-0.8%).

  The opinion was adopted.[2]

- **Update of the "Guidance for the preparation of dossiers for technological additives" to include the new functional group "substances for reduction of the contamination of feed by mycotoxins" (EFSA-Q-2010-00017) and Update of the "Guidance for the preparation of dossiers by categories of feed additives – Technological additives" (EFSA-Q-2010-00902)**

  The Rapporteur presented the questions. Both questions are self-tasks of the Panel intended to update the guidance for the preparation of dossiers for technological additives to take into account the experience of the Panel in the assessment of technological additives and to include the requirements for the new functional group of 'substances for reduction of the contamination of feed by mycotoxins'.

  The proposed modifications were reviewed and discussed. The Panel agreed to adopt this opinion together with the revisions of the other guidance documents currently underway.

- **Optiphos (6-phytase) for chickens and turkeys for fattening, chickens reared for laying, laying hens, turkeys reared for breeding, other birds for fattening and laying, piglets (weaned), pigs for fattening and sows (EFSA-Q-2010-00152)**

  This question refers to the authorisation under Article 4(1) of Regulation (EC) No 1831/2003 of the product Optiphos (6-phytase), produced by a genetically modified strain of *Pichia pastoris*, as a zootechnical additive for poultry and pigs. The safety of the genetic

[1] http://www.efsa.europa.eu/en/events/event/110614-m.pdf

[2] http://www.efsa.europa.eu/en/efsajournal/pub/2415.htm

modification was assessed by the GMO Panel.

The draft opinion was initially considered in the Plenary meeting in April. The final discussion took place and it was concluded that additive is safe for the target species, the consumer and the environment. The concerns for users are limited to its potential to be a respiratory sensitizer. The additive is considered to be efficacious in the target species.

The opinion was adopted.[3]

- **Chemically defined flavourings from Chemical Group 18 – Allylhydroxybenzenes for all animal species and categories (EFSA-Q-2010-00815)**

  The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and authorisation of new use under Article 4 of Regulation (EC) No 1831/2003 of the flavourings from the Chemical Group 18 as sensory additives for all species.

  The draft opinion was discussed. Given time constrains it was decided to continue the discussion during the next plenary meeting.

- **Chemically defined flavourings from Flavouring Group 27 - Anthranilate derivatives for all animal species and categories (EFSA-Q-2010-00990)**

  Not discussed due to lack of time.

- **Update of the "Guidance for the preparation of dossiers by categories of feed additives – Sensory additives" (EFSA-Q-2010-01157)**

  Not discussed due to lack of time.

- **Update of the "Guidance for the preparation of dossiers by categories of feed additives – Nutritional additives" (EFSA-Q-2010-01158)**

  Not discussed due to lack of time.

- **Update of the "Guidance for the preparation of dossiers by categories of feed additives – Zootechnical additives" (EFSA-Q-2010-01159)**

  Not discussed due to lack of time.

- **Update of the "Technical guidance on User safety" (EFSA-Q-2010-01162)**

  Not discussed due to lack of time.

- **Naringin for all animal species (EFSA-Q-2010-01220)**

  The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and authorisation of new use under Article 4 of Regulation (EC) No 1831/2003 of naringin as a sensory additive for all species.

  The draft opinion was discussed. The FEEDAP Panel concluded that the proposed use levels of 1 to 5 mg naringin/kg feed are safe for all animal species with a considerable margin of safety. The additive is considered safe for the consumers and the environment. In solid form the additive should be considered as a possible eye and respiratory irritant. Since its function in feed is essentially the same as that in food, naringin is considered efficacious when used in feed. However, in the absence of data no conclusions on the safety and efficacy of the product when delivered in water for drinking could be drawn.

[3] http://www.efsa.europa.eu/en/efsajournal/pub/2414.htm

The opinion was adopted.[4]

- ***Lactobacillus plantarum* DSM 8862 and *Lactobacillus plantarum* DSM 8866 (Biosil®) for pigs, bovines, sheep, goats and horses (EFSA-Q-2011-00186)**

  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 the preparation containing two strains of *Lactobacillus plantarum* (DSM 8862 and DSM 8866) as silage additive for all pigs, bovines, sheep, goats and horses.

  The draft opinion was discussed. The Panel concluded that the active agent fulfils the requirements of the QPS approach to safety assessment and therefore the use of the strain in the production of silage is considered safe for the target species, the consumer and the environment. Due to its proteinaceous nature, the active agent has the potential to be a skin/respiratory sensitiser. The Panel also concluded that the additive has the potential to improve the production of silage from all forages by reducing the pH and increasing the preservation of dry matter.

  The opinion was adopted.[5]

- **Vitamin B_1 (thiamine mononitrate and thiamine hydrochloride) for all animal species (Lohmann Animal Health) (EFSA-Q-2011-00253)**

  The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and for the authorisation of a new use under Article 4 of Regulation (EC) No 1831/2003 of the product vitamin B_1 as a nutritional additive for all species.

  The draft opinion was discussed. The Panel concluded that thiamine mononitrate administered via feed and thiamine hydrochloride via feed or water for drinking are safe for the target animals with a wide margin of safety. The use of thiamine mononitrate and thiamine hydrochloride as additives in animal nutrition is safe for consumers and the environment. In the absence of data on inhalation toxicity for both compounds, inhalation of dust is considered as potentially hazardous. Thiamine mononitrate and thiamine hydrochloride are regarded as skin and eye irritants, and skin sensitizers. Thiamine mononitrate and thiamine hydrochloride are regarded as effective sources of vitamin B_1.

  The opinion was adopted.[6]

- **Vitamin B_1 (thiamine mononitrate) for all animal species (VITAC EEIG) (EFSA-Q-2011-00254)**

  The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and for the authorisation of a new use under Article 4 of Regulation (EC) No 1831/2003 of the product vitamin B_1 as a nutritional additive for all species.

  The draft opinion was discussed. The Panel concluded that thiamine mononitrate administered via feed or water for drinking is safe for the target animals with a wide margin of safety. The use of thiamine mononitrate as an additive in animal nutrition is safe for consumers and the environment. In the absence of data on inhalation toxicity of thiamine mononitrate, inhalation of dust is considered as potentially hazardous. Thiamine mononitrate is regarded as a skin and eye irritant and a skin sensitizer. The Panel also concluded that

[4] http://www.efsa.europa.eu/en/efsajournal/pub/2416.htm
[5] http://www.efsa.europa.eu/en/efsajournal/pub/2408.htm
[6] http://www.efsa.europa.eu/en/efsajournal/pub/2412.htm

thiamine mononitrate is an effective source of vitamin B_1.

The opinion was adopted.[7]

- **Vitamin B1 (thiamine mononitrate and thiamine hydrochloride) for all animal (DSM Nutritional Products) (EFSA-Q-2011-00255)**

  The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and for the authorisation of a new use under Article 4 of Regulation (EC) No 1831/2003 of the product vitamin B_1 as a nutritional additive for all species.

  The draft opinion was discussed. The Panel concluded that thiamine mononitrate administered via feed and thiamine hydrochloride via water for drinking are safe for the target animals with a wide margin of safety. The use of thiamine mononitrate and thiamine hydrochloride as additives in animal nutrition is safe for consumers and the environment. In the absence of data on inhalation toxicity of thiamine mononitrate and thiamine hydrochloride, inhalation of dust is considered as potentially hazardous. Thiamine mononitrate and thiamine hydrochloride are regarded as skin and eye irritants, and skin sensitizers. Both compounds are considered as effective sources of vitamin B_1.

  The opinion was adopted.[8]

- **Pantothenic acid (calcium D-pantothenate and D-panthenol) for all animal species (Lohmann Animal Health) (EFSA-Q-2011-00256)**

  The Rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4(1) and re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003, of the product pantothenic acid (calcium D-pantothenate and D-panthenol) as nutritional additive for all animal species.

  The draft opinion has been initially considered in the Plenary meeting in May. The final discussion took place and the Panel concluded that the use of calcium D-pantothenate in feed and of D-panthenol in water for drinking is safe for the target species, consumer and environment. In the absence of data on acute inhalation toxicity of calcium D-pantothenate, inhalation of dust is considered as potentially hazardous. Both calcium D-pantothenate and D-panthenol are considered as skin and eye irritants and potential skin sensitisers. Calcium D-pantothenate is regarded as effective source of pantothenic acid and D-panthenol is considered a pro-vitamin essentially bioequivalent to pantothenic acid.

  The opinion was adopted.[9]

- **Pantothenic acid (calcium D-pantothenate and D-panthenol) for all animal species (VITAC EEIG) (EFSA-Q-2011-00257)**

  The Rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4(1) and re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003, of the product pantothenic acid (calcium D-pantothenate and D-panthenol) as nutritional additive for all animal species.

  The draft opinion was initially considered in the Plenary meeting in April. The final discussion took place and the FEEDAP Panel concluded that the use of calcium D-pantothenate in feed and water for drinking and of D-panthenol in water for drinking is safe for the target species, consumer and environment. Data from an acute inhalation toxicity

[7] http://www.efsa.europa.eu/en/efsajournal/pub/2412.htm
[8] http://www.efsa.europa.eu/en/efsajournal/pub/2413.htm
[9] http://www.efsa.europa.eu/en/efsajournal/pub/2409.htm

study allowed to consider the substance of low toxicity by inhalation. Calcium D-pantothenate is not regarded as an irritant to skin and eyes but is considered as a skin sensitizer, D-panthenol is considered as a skin and eye irritant and a potential skin sensitiser. Calcium D-pantothenate is regarded as effective source of pantothenic acid and D-panthenol is considered a pro-vitamin essentially bioequivalent to pantothenic acid.

The opinion was adopted.[10]

5.2. Discussion of the following scientific opinions

- **Biogalactosidase BL (alpha-galactosidase and 1,4-beta-glucanase) for chickens for fattening (EFSA-Q-2009-00534)**

  Not discussed due to lack of time.

- **QuantumTM (6-phytase) for turkeys for fattening (EFSA-Q-2011-00148)**

  Not discussed due to lack of time.

6. PROGRESS REPORT ON ONGOING WORK

Not discussed

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 were presented to the Panel, who accepted them:

EFSA-Q-Number	Subject
EFSA-Q-2011-01090	Rovelan® (Calcium formate) for piglets (weaned), calves for fattening and rearing
EFSA-Q-2011-00991	L-lysine and related compounds // Lysine (Concentrated liquid L-lysine (base), L-lysine monohydrochloride, technically pure, L-lysine sulphate produced by fermentation with Corynebacterium glutamicum (solid form and liquid form)) for all animal species
EFSA-Q-2011-00992	L-lysine and related compounds // Concentrated liquid L-lysine (base) for all animal species
EFSA-Q-2011-00993	L-lysine and related compounds // Concentrated liquid L-lysine-monohydrochloride for all animal species
EFSA-Q-2011-00994	L-lysine and related compounds // L-lysine-monohydrochloride, technically pure for all animal species
EFSA-Q-2011-00995	L-lysine and related compounds // L-lysine (L-lysine monohydrochloride and L-lysine sulphate) for all animal species
EFSA-Q-2011-00996	L-lysine and related compounds // L-lysine (L-lysine monohydrochloride and L-lysine sulphate) for all animal species

[10] http://www.efsa.europa.eu/en/efsajournal/pub/2410.htm

8.2. 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
EFSA-Q-2011-01071	Astaxanthin // Astaxanthin (Carophyll® Pink 10% CWS) for salmonids and ornamental fish	05/10/2011
EFSA-Q-2011-00965	Fecibiol® and Fecibiol® plus (*Enterococcus faecium* CECT 4515 and *Bacillus amyloliquefaciens* CECT 5940) for pets and fur animals	30/09/2011
EFSA-Q-2011-00964	Protural (Sodium benzoate) for piglets (weaned)	14/09/2011
EFSA-Q-2011-00952	Vitamin D3 // Vitamin D3 (cholecalciferol) for all animal species	30/09/2011
EFSA-Q-2011-00951	Vitamin D3 // Vitamin D3 for pigs, piglets, bovines, ovines, calves, equines, chickens for fattening, turkeys, other poultry, fish, other species or categories of animals	30/09/2011
EFSA-Q-2011-00950	Vitamin D3 // Vitamin D3 (cholecalciferol) for chickens for fattening, turkeys, other poultry, piglets (suckling), pigs, calves for rearing, calves for fattening, bovines, ovines, equines, all fish species or categories	30/09/2011
EFSA-Q-2011-00942	Butylated Hydroxy Anisole (BHA) for all animal species and categories	13/09/2011
EFSA-Q-2011-00841	Sorbic acid and salts of sorbic acid // Potassium sorbate for all animal species except dogs and cats	30/09/2011
EFSA-Q-2011-00840	Sorbic acid and salts of sorbic acid // Sorbic acid and potassium sorbate for all animal species	30/09/2011
EFSA-Q-2011-00839	Sorbic acid and salts of sorbic acid // Sorbic acid for all animal species	30/09/2011
EFSA-Q-2011-00838	Sorbic acid and salts of sorbic acid // Potassium sorbate for all animal species	30/09/2011
EFSA-Q-2011-00837	Sorbic acid and salts of sorbic acid // Potassium sorbate for all animal species	30/09/2011
EFSA-Q-2011-00836	Sorbic acid and salts of sorbic acid // Potassium sorbate for dogs and cats	30/09/2011
EFSA-Q-2011-00835	Phyzyme XP 5000 L, Phyzyme XP 5000 G, Phyzyme XP 10000 L and Phyzyme XP 10000 TPT (6-phytase) for all minor poultry species	28/09/2011
EFSA-Q-2011-00805	Lantharenol® (Lanthanum carbonate octahydrate) for dogs	28/09/2011
EFSA-Q-2011-00804	Avemix® XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for laying hens and minor poultry species	15/09/2011
EFSA-Q-2011-00743	Copper E 4 // Cupric sulphate, pentahydrate for all animal species	21/09/2011
EFSA-Q-2011-00742	Copper E 4 // Copper amino acid chelate, hydrate (Availa® Cu) for all animal species	21/09/2011
EFSA-Q-2011-00741	Copper E 4 // Copper (cupric acetate monohydrate, basic cupric carbonate monohydrate, cupric chloride, dihydrate, cupric oxide, cupric sulphate, pentahydrate, cupric chelate of amino acids hydrate, cupric chelate of glycine hydrate (solid), cupric chelate of glycine hydrate (liquid)) for all animal species	21/09/2011
EFSA-Q-2010-01532	Endo-1,4-beta-xylanase (Safizym X®) for chickens for fattening, turkeys for fattening, laying hens.	16/09/2011
EFSA-Q-2010-01529	Patent Blue V for all animal species	05/09/2011
EFSA-Q-2010-01526	Brilliant Black PN for all animal species	05/09/2011

EFSA-Q-2010-01523	Quinoline yellow for all animal species	05/09/2011
EFSA-Q-2010-01520	Smoke flavouring (Scansmoke SEF 7525) for cats and dogs	15/09/2011

8.3. Questions under Regulation (EC) No 767/2009

EFSA-Q-Number	Subject
EFSA-Q-2011-01075	Evaluation of the safety of leaves of *Solanum glaucophyllum*

9. GENERAL INFORMATION FROM EFSA

There was a presentation on the new webconference tool.

10. EMERGING RISKS

Not discussed.

11. MISCELLANEOUS

- A discussion took place on the need to review the assessment of consumer safety from the opinion on "Safety and efficacy of Sel-Plex® (organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060) for all species"[11]. After an extended consideration of the data and arguments provided by the applicant and a discussion held in the plenary, the Panel did not see reasons to update the opinion. The EC will be informed.

[11] http://www.efsa.europa.eu/en/efsajournal/doc/2110.pdf