# MINUTES OF THE 86TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (FEEDAP)

## (PARMA, 22-24 MAY 2012)

### (AGREED ON 12 JUNE 2012)

## PARTICIPANTS

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

Apologies
Joop de Knecht, Anne-Katrine Lundebye Haldorsen (3rd day), Alberto Mantovani (3rd day) and Johannes Westendorf (3rd day).

EFSA
Claudia Roncancio-Peña, Jaume Galobart, Gloria López-Gálvez, Paola Manini, Rosella Brozzi, Matteo Lorenzo Innocenti, Lucilla Gregoretti and Nicola Jane Reynolds.

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### 1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 86th Plenary meeting of the FEEDAP Panel.

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

The FEEDAP Panel expressed their sincere condolences to the family of Prof. Reinhard Kroker who passed away unexpectedly in the last days. Prof. Kroker was well known in the scientific community and his expertise was widely recognised. His extensive knowledge was much in demand and at the Panel was delighted that he was able to contribute to its work. He made a much valued contribution to the work of Panel since 2009, which benefitted enormously from his expertise.

### 2. ADOPTION OF THE AGENDA

The agenda was adopted after the removal of the items Chemically defined flavourings from Chemical Group 13 - Furanones and tetrahydrofurfuryl derivates for all animal species and categories (EFSA-Q-2010-01169); Cupric sulphate pentahydrate for all animal species (EFSA-Q-2011-00743); Zinc oxide for all species (EFSA-Q-2011-00844) and Bactocell (*Pediococcus acidilactici*) for fish (EFSA-Q-2012-00441).

## 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 85TH PLENARY MEETING

The minutes of the 85th Plenary meeting of the Panel held on 24-26 April 2012 were reviewed and agreed.[1]

## 5. WORK PROGRAM

### 5.1. Discussion and possible adoption of the following scientific opinions

- **Beta-carotene for all animal species (EFSA-Q-2009-00884)**

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

  The draft opinion was discussed. The Panel concluded that the use of beta-carotene is safe for the target animals. Setting a maximum content in feed legislation is not considered necessary. However, this conclusion assumes that triphenylphosphine oxide does not exceed 100 mg/kg additive. The current database did not allow setting an ADI for beta-carotene, therefore the FEEDAP Panel considers it prudent that supplemental beta-carotene in animal feed should not significantly add to consumer exposure from other sources. The use of supplemental beta-carotene in feeds of food-producing animals, except veal calves, would not result in a significant additional exposure of consumers to beta-carotene. Beta-carotene is not an irritant to eyes or skin and is not a skin sensitiser but is considered potentially hazardous through respiratory exposure. The use of beta-carotene in animal nutrition at the recommended feed concentrations would not pose a risk to the environment. Beta-carotene is utilised for the synthesis of retinol in almost all animal species except the cat.

  The opinion was adopted.[2]

- **Ronozyme Rumistar (alpha-amylase) for lactating cows (EFSA-Q-2010-00139)**

  Not discussed due to lack of time.

- **Selemax 1000/2000 (Selenium enriched yeast, *Saccharomyces cerevisiae* YSC 11111-R646) for all animal species. (EFSA-Q-2010-01029)**

  Not discussed due to lack of time.

- **Taurine for all animal species (EFSA-Q-2010-01299)**

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

  The draft opinion was discussed. The Panel concluded that in the cat, dietary taurine at requirement/allowance levels is safe with a margin of safety between 4 and 20. For carnivorous fish levels between 2.0 and 2.5 % are considered safe and with the limited data

[1] http://www.efsa.europa.eu/en/events/event/120424-m.pdf

[2] http://www.efsa.europa.eu/en/efsajournal/pub/2737.htm

available, it has been concluded that up to 0.2 % taurine in feed is tolerated by all animal species. The use of taurine as an additive for all animal species would not raise concerns to consumer safety and does not pose a risk to the environment. In the absence of data, taurine is considered as a skin and eye irritant and skin sensitiser, and as hazardous by inhalation. Taurine is considered efficacious for its use in diet for cats, dogs and carnivorous fish. For poultry, pigs and ruminants no studies were found to demonstrate beneficial effects of taurine supplementation on performance, health or product quality of these animal species.

The opinion was adopted.[3]

- **Ammonium chloride for bovines, sheep, cats and dogs (EFSA-Q-2010-01515)**

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and authorisation of a new use under Article 4 of Regulation (EC) No 1831/2003 of ammonium chloride as a technological additive for bovines, sheep, cats and dogs.

The draft opinion was discussed. The Panel concluded that a feed concentration of 1 % ammonium chloride is considered safe for ruminants for approximately three months. For an unlimited period of administration, a level of 0.5 % ammonium chloride in complete feed for ruminants, cats and dogs should not be exceeded. The use of ammonium chloride in animal nutrition does not raise concerns to consumer safety. Ammonium chloride is an eye irritant, a potential irritant to skin and the digestive tract, potentially harmful if swallowed and may cause systemic toxicity by acidosis. It should be considered as a skin sensitizer and its fumes are regarded as a potential respiratory sensitiser. The use of ammonium chloride at dietary levels considered safe for ruminants does therefore not pose a risk for the environment. The FEEDAP Panel also concluded that the efficacy of the additive as acidity regulator of feed is not demonstrated. However, ammonium chloride effectively reduces the urinary pH in ruminants, dogs and cats.

The opinion was adopted.[4]

- **Smoke flavouring (Scansmoke SEF 7525) for cats and dogs (EFSA-Q-2010-01520)**

The Chair of the Working Group (WG) presented the question and the draft opinion. This question refers to the authorisation of a new feed additive under Article 4 of Regulation (EC) No 1831/2003 of the smoke flavouring "Scansmoke SEF 7525" as a sensory additive for cats and dogs.

The draft opinion was discussed. The Panel concluded that "Scansmoke SEF 7525" is safe for the target species at 40 mg/kg complete feed. The Panel considers it prudent to treat the product under assessment as irritant to skin, eye and respiratory tract, a skin sensitiser and harmful if swallowed. The Panel considers it efficacious when used in feed. The Panel recommended that the level of residual solvent follows the VICH guidance. This assessment applies only to Scansmoke SEF7525 and cannot be extrapolated to other smoke flavours.

The opinion was adopted.[5]

- **Nicotinamide for all animal species (EFSA-Q-2011-00265)**

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003 of the product niacin

[3] http://www.efsa.europa.eu/en/efsajournal/pub/2736.htm
[4] http://www.efsa.europa.eu/en/efsajournal/pub/2738.htm
[5] http://www.efsa.europa.eu/en/efsajournal/pub/2729.htm

(nicotinamide) as a nutritional additive for all species.

The draft opinion was discussed. The Panel concluded that nicotinamide is safe for the target animals with a margin of safety of at least ten-fold the requirements and use levels. The FEEDAP Panel considered that the use of niacin in animal nutrition is not of safety concern for consumers and does not pose a risk to the environment. Nicotinamide is not irritant to skin, but can cause irritancy to eyes and mucous membranes. It is unlikely to cause skin sensitisation. The product is unlikely to form dust particles of respirable size. Nicotinamide is regarded as an effective source of niacin in animal nutrition.

The opinion was adopted.[6]

- **Cobalt carbonate for ruminants, horses and rabbits (EFSA-Q-2011-00332)**

  The rapporteur presented the question and the draft opinion. This question refers to the authorisation of a new feed additive under Article 4 of Regulation (EC) No 1831/2003 of cobalt carbonate as a nutritional additive for ruminants, horses and rabbits.

  The draft opinion was discussed. Dietary cobalt is needed for ruminants, rabbits and horses to synthesise vitamin $B_{12}$. The FEEDAP Panel concluded that cobalt carbonate 46 % is safe for target species. The additive does not pose any safety concern for the consumer for threshold effects; however, due to toxicological concerns and uncertainties related to cobalt(II) and its salts, the Panel confirmed its previous position recommending to limit the cobalt supplementation of feedingstuffs to a level lower than the current maximum authorised. The additive is considered a carcinogen by inhalation, mutagenic and a reproduction toxicant. It is considered as a skin and eye irritant and as dermal and respiratory sensitizer. Exposure by inhalation must be avoided. The additive is not expected to pose a risk for the environment. It is an efficacious nutritional additive for the target species.

  The opinion was adopted.[7]

- **18 strains of *Lactobacillus plantarum* (DSM 23375, CNCM I-3235, DSM 19457, DSM 16568, LMG 21295, DSM 16565, VTT E-78076, CNCM MA 18/5U, NCIMB 30238, ATTC PTA-6139, DSM 18112, ATCC 55058, DSM 18113, DSM 18114, ATCC 55942, ATCC 55943, ATCC 55944 and NCIMB 30094) as silage additives for all species (EFSA-Q-2011-00374)**

  The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2)/(7) of Regulation (EC) No 1831/2003 of 18 strains of *Lactobacillus plantarum* as silage additives for all species.

  The draft opinion was discussed. The FEEDAP Panel concluded that the 18 strains are presumed safe for livestock species, consumers of products from animals fed the treated silage and for the environment. Given the dusting potential and proteinaceous nature of the active agents, the FEEDAP Panel concluded that all 18 additives should be considered as skin and respiratory sensitisers. Nine of 18 additives showed a potential at the respective minimum doses proposed to improve the production of silage from a wide range of forage species by reducing the pH and increasing the preservation of dry matter. Another strain also showed a similar potential but only when used in combination with a specific strain of *Pediococcus pentosaceus*. Of the remaining strains, six were tested only with easy to ensile material. Although all six showed a potential to improve ensiling, the FEEDAP Panel

[6] http://www.efsa.europa.eu/en/efsajournal/pub/2731.htm

[7] http://www.efsa.europa.eu/en/efsajournal/pub/2727.htm

concluded that further evidence would be required to justify a claim for use with "all forage species". The Panel was unable to conclude on the efficacy of the remaining two strains.

The opinion was adopted.[8]

- **AveMix XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for laying hens and minor poultry species (EFSA-Q-2011-00804)**

  The rapporteur presented the question and the draft opinion. This question refers to the authorisation of a new use under Article 4 of Regulation (EC) No 1831/2003 of the product AveMix XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) as a zootechnical additive for laying hens and minor poultry species.

  The draft opinion was discussed. The safety of this product for the consumer, user and the environment has already been assessed.[9] The FEEDAP Panel concluded that the additive is safe and efficacious when used in feed for laying hens and minor poultry species.

  The opinion was adopted.[10]

- **Potassium sorbate for dogs and cats (EFSA-Q-2011-00836)**

  The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003 of potassium sorbate as a technological additive for cats and dogs.

  The draft opinion was discussed. The Panel concluded that potassium sorbate is safe for both dogs and cats at a maximum level of 5 000 mg/kg semi-moist complete feed. Potassium sorbate is a skin and eye irritant and a potential irritant for the respiratory tract. The FEEDAP Panel also concluded that potassium sorbate has the potential to act as preservative in semi-moist feed for dogs and cats.

  The opinion was adopted.[11]

- **Zinc sulphate monohydrate for all animal species (EFSA-Q-2011-00842)**

  The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003 of zinc sulphate monohydrate (based on a dossier submitted by Grillo-Werke AG/EMFEMA) as a nutritional additive for all animal species.

  The draft opinion was discussed. The FEEDAP Panel concluded that the additive is safe for the target species, consumer and users. The use of zinc as a feed additive does not pose direct concern for agricultural soil compartment. However, there is a potential environmental concern related to drainage and run-off of zinc to surface water. The use of zinc-containing feed additives in aquaculture up to maximum authorised zinc level in feeds is not expected to pose an appreciable risk to the environment. Zinc sulphate monohydrate is an efficacious source of zinc in meeting animal requirements.

  The opinion was adopted.[12]

- ***Pediococcus acidilactici* (CNCM I-3237, CNCM MA 18/5M – DSM 11673) and *Pediococcus pentosaceus* (DSM 23376, NCIMB 12455, NCIMB 30237 and NCIMB**

[8] http://www.efsa.europa.eu/en/efsajournal/pub/2732.htm
[9] http://www.efsa.europa.eu/en/efsajournal/pub/1094.htm
[10] http://www.efsa.europa.eu/en/efsajournal/pub/2728.htm
[11] http://www.efsa.europa.eu/en/efsajournal/pub/2735.htm
[12] http://www.efsa.europa.eu/en/efsajournal/pub/2734.htm

**30168) as a silage additive for all species (EFSA-Q-2011-00940)**

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2)/(7) of Regulation (EC) No 1831/2003 of two strains of *Pediococcus acidilactici* and four strains of *Pediococcus pentosaceus* as silage additives for all species.

The draft opinion was discussed. The FEEDAP Panel concluded that the six strains are presumed safe for livestock species, consumers of products from animals fed the treated silage and for the environment. Given the dusting potential and proteinaceous nature of the active agents, the FEEDAP Panel concluded all additives should be considered as skin and respiratory sensitisers. One strain of *P. acidilactici* and three strains of *P. pentosaceus* were shown to have the potential to improve the production of silage from easy, moderately difficult and difficult to ensile forage species by reducing the pH and increasing the preservation of dry matter and/or protein, when used at the doses proposed. Another strain of *P. pentosaceus* appeared to favourably affect the ensiling process by reducing the pH, but only when used in combination with a specific strain of *Lactobacillus plantarum*. However, the consequences of a more rapid pH reduction for the preservation of nutrients were not shown. Data for the remaining strain of *P. acidilactici* were partly contradictory and inconsistent and no conclusions on efficacy could be drawn.

The opinion was adopted.[13]

- **Guidance on the assessment of bacterial susceptibility to antimicrobials (EFSA-Q-2011-01108)**

The rapporteur presented the question. The Panel through this self-task intends to update the guidance for the assessment of bacterial resistance to antibiotics of human and veterinary importance.

The comments received during the public consultation were presented to the Panel and the changes introduced in the guidance were reviewed.

The guidance was adopted.[14]

- **Danisco Xylanase 40000 G/L (endo-1,4-beta-xylanase) laying hens and all minor poultry species (EFSA-Q-2011-01171)**

The rapporteur presented the question and the draft opinion. This question refers to the authorisation of a new use under Article 4 and the modification of the terms of the authorisation under Article 13(3) of Regulation (EC) No 1831/2003 of the product Danisco Xylanase 40000 G/L (endo-1,4-beta-xylanase) as a zootechnical additive for laying hens and minor poultry species. This product is authorised for use in chickens for fattening, laying hens, ducks and turkeys for fattening, weaned piglets and pigs for fattening. The applicant is seeking a modification of the current authorisation for laying hens (reduction of the minimum dose) and an extension of the authorisation to all poultry minor species.

The draft opinion was discussed. The safety of this product for the consumer, user and the environment has already been assessed.[15] The FEEDAP Panel concluded that the additive is safe for all minor poultry species. Based on the results of a meta-analysis, the Panel also concluded that the additive has the potential to be efficacious at the new minimum proposed dose for laying hens. The Panel extended the conclusion on efficacy of the major species to all minor poultry species.

[13] http://www.efsa.europa.eu/en/efsajournal/pub/2733.htm
[14] http://www.efsa.europa.eu/en/efsajournal/pub/2740.htm
[15] http://www.efsa.europa.eu/de/scdocs/doc/548.pdf

The opinion was adopted.[16]

- **Ronozyme HiPhos GT (6-phytase) poultry and pigs (EFSA-Q-2011-01172)**

  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 the product Ronozyme HiPhos GT (6-phytase) as a zootechnical additive for all poultry and pigs. This product is already authorised for the same target species in a solid and a liquid forms (M and L). The applicant is now seeking for the authorisation of a new solid formulation (GT).

  The draft opinion was discussed. The Panel considered that the new formulation is not expected to introduce hazards to the target species, consumers, users and the environment not already considered in the previous application. The new formulation is expected to be as efficacious as the other two, and this has been confirmed in two efficacy studies with the GT form.

  The opinion was adopted.[17]

## 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-2012-00557 | Coxidin® (Monensin sodium) for chickens for fattening, chickens reared for laying, turkeys |
| EFSA-Q-2012-00575 | Miya-Gold® (*Clostridium butyricum* MIYAIRI 588 (FERM BP-2789) for chickens for fattening, chickens reared for laying, minor avian species for fattening and to point of lay |

### 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-2011-00279 | Sodium hydroxide for cats, dogs and ornamental fish | 08/05/2012 |
| EFSA-Q-2011-01147 | Sodium metabisulphite for dogs and cats | 23/04/2012 |
| EFSA-Q-2012-00081 | *Pediococcus pentosaceus* NCIMB 30068 for all animal species | 14/05/2012 |

[16] http://www.efsa.europa.eu/en/efsajournal/pub/2739.htm
[17] http://www.efsa.europa.eu/en/efsajournal/pub/2730.htm

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|---|---|---|
| EFSA-Q-2012-00082 | *Lactobacillus paracasei* NCIMB 30151 for all animal species | 14/05/2012 |
| EFSA-Q-2012-00083 | *Lactobacillus plantarum* DSMZ 16627 for all animal species | 14/05/2012 |
| EFSA-Q-2012-00084 | *Pediococcus acidilactici* NCIMB 30005 for all animal species | 14/05/2012 |
| EFSA-Q-2012-00085 | *Lactobacillus fermentum* NCIMB 30169 for all animal species | 14/05/2012 |
| EFSA-Q-2012-00086 | *Lactobacillus brevis* DSMZ 16680 for all animal species | 14/05/2012 |
| EFSA-Q-2012-00087 | *Pediococcus pentosaceus* NCIMB 30044 (formerly *Lactococcus lactis lactis* NCIMB 30044)for all animal species | 14/05/2012 |
| EFSA-Q-2012-00113 | L-threonine for all animal species | 27/04/2012 |
| EFSA-Q-2012-00114 | L-threonine, technically pure for all animal species | 27/04/2012 |
| EFSA-Q-2012-00115 | L-threonine, technically pure for all animal species | 27/04/2012 |
| EFSA-Q-2012-00116 | L-threonine, technically pure for all animal species | 27/04/2012 |
| EFSA-Q-2012-00117 | L-threonine, technically pure for all animal species | 27/04/2012 |
| EFSA-Q-2012-00118 | L-Threonine, technically pure (ThreAMINO®) for all animal species | 27/04/2012 |
| EFSA-Q-2012-00244 | Hemicell® (endo-1,4-beta-mannanase) for weaned piglets, pigs for fattening, minor porcine species, laying hens, turkeys for fattening, minor avian species | 08/05/2012 |
| EFSA-Q-2012-00253 | Bactocell (*Pediococcus acidilactici* CNCM MA 18/5M) for pigs for fattening, piglets (weaned), chickens for fattening and laying hens | 08/05/2012 |
| EFSA-Q-2012-00287 | LANCER (Lanthanide-citrate) for piglets (weaned) | 11/05/2012 |
| EFSA-Q-2012-00411 | Alpha-amylase produced by *Aspergillus oryzae* DS 114; Alpha-amylase produced by *Aspergillus oryzae* CBS 585.94; Alpha-amylase produced by *Bacillus amyloliquefaciens* SD80; Alpha-amylase produced by *Bacillus amyloliquefaciens* DSM 9553; Alpha-amylase produced by *Bacillus subtilis* DS 098; Cellulase produced by *Trichoderma longibrachiatum* ATCC PTA-10001; Cellulase produced by *Trichoderma longibrachiatum* ATCC 74252; Cellulase produced by *Aspergillus niger* CBS 120604 294; Beta-glucanase produced by *Aspergillus niger* MUCL 39199; Xylanase produced by *Trichoderma longibrachiatum* Rifar IMI SD185; Xylanase produced by *Trichoderma longibrachiatum* MUCL 39203 and Xylanase produced by *Trichoderma longibrachiatum* CBS 614.94 for all animal species | 26/04/2012 |
| EFSA-Q-2012-00414 | Fumaric Acid for all animal species | 26/04/2012 |
| EFSA-Q-2012-00415 | Hexamethylene tetramine for pigs, poultry, bovines, ovines, goats, rabbits and horses | 26/04/2012 |
| EFSA-Q-2012-00419 | Cylactin®/Cernivet® (*Enterococcus faecium* NCIMB 10415) for piglets (suckling and weaned), pigs for fattening and sows | 02/05/2012 |

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|---|---|---|
| EFSA-Q-2012-00420 | Cylactin® LBC ME5 PET / Cernivet® LBC ME5 PET (*Enterococcus faecium* NCIMB 10415) for dogs and cats | 30/04/2012 |
| EFSA-Q-2012-00422 | Fecinor® and Fecinor® plus (*Enterococcus faecium* CECT 4515) for piglets (weaned) | 26/04/2012 |
| EFSA-Q-2012-00455 | Vitamin B12 (cyanocobalamin) for all animal species | 04/05/2012 |
| EFSA-Q-2012-00456 | Vitamin B12 (cyanocobalamin) for all animal species | 04/05/2012 |
| EFSA-Q-2012-00457 | Vitamin B12 (cyanocobalamin) for all animal species | 04/05/2012 |

## 9. GENERAL INFORMATION FROM EFSA

Not discussed

## 10. EMERGING RISKS

Not discussed.

## 11. MISCELLANEOUS

- The next Plenary meeting will be extended by one day (12-15 June).