# MINUTES OF THE 78TH PLENARY MEETING

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

## (BERLIN, 14-16 JUNE 2011)

### (AGREED ON 6 SEPTEMBER 2011)

## PARTICIPANTS

Panel Members

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

Apologies

Pier Sandro Cocconcelli (3rd day), Noel Dierick, Maria Saarela, Anne-Katrine Lundebye Haldorsen (3rd day) and Johannes Westendorf.

EFSA

Claudia Roncancio-Peña, Matteo Lorenzo Innocenti and Gloria López-Gálvez.

European Commission

Marta Ponghellini (DG SANCO) and Christoph von Holst (DG JRC) (2nd day)

---

### 1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 78th Plenary meeting of the FEEDAP Panel.He also thanked the German Federal Institute for Risk Assessment (BfR) for the invitation to held the plenary in Berlin.

Professor Dr. Andreas Hensel the President of BfR and Priv. Doz. Dr. Helmut Schafft, Feed and Feed Additives Unit, welcomed the FEEDAP Panel and the Secretariat to Berlin and to BfR premises.

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

### 2. ADOPTION OF THE AGENDA

The agenda was adopted.

### 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 77TH PLENARY MEETING

The minutes of the 77th Plenary meeting of the Panel held on 10-12 May 2011 were reviewed and agreed.[1]

## 5. WORK PROGRAM

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

- **SelenoSource AF 2000 (selenomethionine) for all animal species (EFSA-Q-2009-00524)**

  The Rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4(1) of Regulation (EC) No 1831/2003 of selenium in the form of organic compounds produced by the selenium-enriched yeast *Saccharomyces cerevisiae* NCYC R645 (SelenoSource AF 2000) as nutritional additive for all animal species.

  The draft opinion was discussed. The FEEDAP Panel could not conclude on the safety for target species and on the safety for the user, due to the absence of data. The Panel concluded that, to ensure consumer safety, dietary selenium supplementation from this additive, as for other selenised yeasts, should not exceed a maximum of 0.2 mg Se/kg complete feed. The product is safe for the environment. SelenoSource AF 2000 is an effective source of selenium for all species.

  The opinion was adopted.[2]

- **Efficacy of Bentonite (dioctahedral montmorillonite) for all animal species (EFSA-Q-2011-00335)**

  The Rapporteur presented the question and the draft opinion. In a previous opinion on the same product,[3] the Panel was not able to give a conclusive opinion on the efficacy of the product for some animal species because of lack of data provided by the company. The applicant has now provided additional data to support the efficacy for all animal species.

  The draft opinion was discussed. The FEEDAP Panel reviewed all data, considerations and statements provided by the applicant. No convincing argument or experimental result could be found which would alter the former position of the Panel. The Panel reiterated therefore, its former conclusion that it can not assess the efficacy of the bentonite under application as aflatoxin binder for any other animal species than ruminants due to the absence of appropriate *in vivo* data.

  The opinion was adopted.[4]

- **AveMix® XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for weaned piglets (EFSA-Q-2010-00018)**

  The Rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4(1) 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 zootechnical additive for weaned piglets.

  The draft opinion was discussed. The safety aspects other than safety for the target species have already been considered in two previous opinions on the same product. Only safety and

[1] http://www.efsa.europa.eu/en/events/event/feedap110511-m.pdf
[2] http://www.efsa.europa.eu/en/efsajournal/pub/2279.htm
[3] http://www.efsa.europa.eu/en/efsajournal/pub/2007.htm
[4] http://www.efsa.europa.eu/en/efsajournal/pub/2276.htm

efficacy for weaned piglets were considered in the opinion. The Panel concluded that AveMix® XG 10 is safe and efficacious for weaned piglets at the recommended dose.

The opinion was adopted.[5]

- **Econase XT (endo-1,4-beta-xylanase) for laying hens, pigs for fattening and minor poultry species (including ducks, geese, quails, pheasants, pigeons) (EFSA-Q-2010-00142)**

  The Rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4(1) of Regulation (EC) No 1831/2003 of the product Econase XT (endo-1,4-beta-xylanase) as zootechnical additive for laying hens, pigs for fattening and minor species including ducks, geese, quails, pheasants, pigeons.

  The draft opinion was discussed. The safety aspects other than safety for the target species have already been considered in two previous opinions on the same product. Only safety and efficacy for the new target species/categories were considered in the opinion. The Panel concluded that the additive is safe for the target species/categories at the maximum recommended dose (24000 BXU/kg). It has the potential to increase the performance of laying hens and pigs for fattening at a dose of 24000 BXU/kg. The efficacy demonstrated in chickens for fattening and in laying hens permitted to extrapolate efficacy to all minor poultry species at 8000 BXU/kg for growing birds and at 24000 BXU/kg for laying birds.

  The opinion was adopted.[6]

- ***Lactobacillus plantarum* NCIMB 30236 for all species (EFSA-Q-2011-00062)**

  The Rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4(1) of Regulation (EC) No 1831/2003 of the product *Lactobacillus plantarum* (NCIMB 30236) as silage additive for all species.

  The draft opinion was discussed. The FEEDAP 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 its proteinaceous nature, the active agent has the potential to be a skin/respiratory sensitizer. The Panel also concluded that the additive has the potential to improve the production of silage from all forages by reducing the pH, increasing the preservation of dry matter and protein.

  The opinion was adopted.[7]

## 5.2. Discussion of the following scientific opinions

- **Propionic acid, sodium propionate, calcium propionate, ammonium propionate for all animal species (EFSA-Q-2010-01302)**

  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 products propionic acid, sodium propionate, calcium propionate, ammonium propionate as technological additive for all animal species.

  A preliminary discussion took place. However, since supplementary information was requested to the applicant on some aspects of the assessment, the opinion will be discussed again in a future plenary.

[5] http://www.efsa.europa.eu/en/efsajournal/pub/2278.htm
[6] http://www.efsa.europa.eu/en/efsajournal/pub/2277.htm
[7] http://www.efsa.europa.eu/en/efsajournal/pub/2275.htm

- **Sodium benzoate, propionic acid, sodium propionate for pigs, poultry, bovines, sheep, goats, rabbits and horses (EFSA-Q-2010-01530)**

  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 sodium benzoate, propionic acid and sodium propionate, for pigs, poultry, bovines, sheep, goats, rabbits, horses.

  The draft opinion was discussed. The opinion will be submitted for adoption once the comments from the Member States and the report from the EURL are received and considered.

- ***Lactobacillus paracasei* (DSM 16773) for all animal species (EFSA-Q-2011-00387)**

  The Rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 10(7) of Regulation (EC) No 1831/2003 of the product *Lactobacillus paracasei* (DSM 16773) as silage additive for all species.

  The draft opinion was discussed. The opinion will be submitted for adoption once the comments from the Member States and the report from the EURL are received and considered.

## 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-2011-00766 | Shellac for all animal species |
| EFSA-Q-2011-00750 | Citric acid and salts of citric acid // Citric acid for all animal species |
| EFSA-Q-2011-00749 | Citric acid and salts of citric acid // Tripotassium citrate for all pet species |
| EFSA-Q-2011-00748 | Citric acid and salts of citric acid // Trisodium citrate dihydrate for dogs and cats |
| EFSA-Q-2011-00747 | Iodine E 2 // Calcium iodate, anhydrous (film granulated preparation) for all animal species |
| EFSA-Q-2011-00746 | Iodine E 2 // Calcium iodate, anhydrous and potassium iodide for all animal species |
| EFSA-Q-2011-00745 | Iodine E 2 // Calcium iodate, anhydrous for all animal species |
| EFSA-Q-2011-00744 | Iodine E 2 // Calcium iodate, anhydrous and potassium iodide for all animal species |

| | |
|---|---|
| EFSA-Q-2011-00743 | Copper E 4 // Cupric sulphate, pentahydrate for all animal species |
| EFSA-Q-2011-00742 | Copper E 4 // Copper amino acid chelate, hydrate (Availa® Cu) for all animal species |
| 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 |

### 8.2. Other mandates

| EFSA-Q-Number | Subject |
|---|---|
| EFSA-Q-2011-00432 | Public consultation on the Technical Guidance on the assessment of the toxigenic potential of *Bacillus* and related genera used in animal nutrition |

### 8.3. 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-2011-00390 | *Saccharomyces cerevisiae* NBRC 0203 (IFO 0203), *Lactobacillus plantarum* NBRC 3070 (ATCC 8014) and *Lactobacillus casei* NBRC 3425 (ATCC 7469) for all animal species | 01/06/2011 |
| EFSA-Q-2011-00389 | *Bacillus amyloliquefaciens* NCIMB 30229 for all animal species | 01/06/2011 |
| EFSA-Q-2011-00388 | *Lactobacillus pentosus* DSM 14025 for all animal species | 24/05/2011 |
| EFSA-Q-2011-00387 | *Lactobacillus paracasei* DSM 16773 for all animal species | 24/05/2011 |
| EFSA-Q-2011-00386 | *Pediococcus pentosaceus* DSM 12834 for all animal species | 01/06/2011 |
| EFSA-Q-2011-00385 | *Lactobacillus brevis* DSM 12835 for all animal species | 01/06/2011 |
| EFSA-Q-2011-00384 | *Lactobacillus plantarum* DSM 12836 for all animal species | 01/06/2011 |
| EFSA-Q-2011-00383 | *Lactococcus lactis* NCIMB 30160 for all animal species | 27/05/2011 |
| EFSA-Q-2011-00382 | *Lactobacillus brevis* IFA 92 - DSM 23231, *Lactobacillus buchneri* CCM 1819 - DSM 22501, *Lactobacillus buchneri* NCIMB 40788 - CNCM I-4323, *Lactobacillus buchneri* - ATCC PTA-6138, *Lactobacillus buchneri* - ATCC PTA-2494 for all animal species | 24/05/2011 |
| EFSA-Q-2011-00381 | *Lactobacillus salivarius* ATCC 11741 / CNCM I-3238 and *Lactobacillus casei* (LC 32909) ATCC PTA-6135 for all animal species | 24/05/2011 |

| | | |
|---|---|---|
| EFSA-Q-2011-00380 | *Lactobacillus rhamnosus* NCIMB 30121 for all animal species | 27/05/2011 |
| EFSA-Q-2011-00379 | *Pediococcus acidilactici* DSM 16243 for all animal species | 27/05/2011 |
| EFSA-Q-2011-00378 | *Lactobacillus paracasei* DSM 16245 for all animal species | 27/05/2011 |
| EFSA-Q-2011-00377 | *Lactobacillus plantarum* DSM 12837 for all animal species | 24/05/2011 |
| EFSA-Q-2011-00376 | *Lactobacillus buchneri* DSM 12856 for all animal species | 27/05/2011 |
| EFSA-Q-2011-00375 | *Lactobacillus buchneri* DSM 16774 for all animal species | 27/05/2011 |
| EFSA-Q-2011-00374 | *Lactobacillus plantarum* (18 strains) for all animal species | 01/06/2011 |
| EFSA-Q-2011-00373 | *Lactococcus lactis* NCIMB 30117 for all animal species | 24/05/2011 |
| EFSA-Q-2011-00334 | Formaldehyde // Formaldehyde (Salmocid®) for all animal species | 06/06/2011 |
| EFSA-Q-2011-00333 | Formaldehyde // Formaldehyde for all animal species | 06/06/2011 |
| EFSA-Q-2011-00199 | Preparation of bentonite - montmorillonite and sepiolite (Toxfin® Dry) for all animal species | 06/06/2011 |
| EFSA-Q-2011-00148 | Quantum™ (6-phytase) for turkeys for fattening | 18/05/2011 |
| EFSA-Q-2011-00061 | Natugrain® TS (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for pigs for fattening | 18/05/2011 |
| EFSA-Q-2010-01515 | Ammonium chloride (Ammoniumchloride AF) for bovines, sheep, cats and dogs | 10/05/2011 |
| EFSA-Q-2010-01304 | *Lactobacillus brevis* DSMZ 21982 for all animal species | 23/05/2011 |
| EFSA-Q-2010-00881 | VevoVitall® (benzoic acid) for piglets (weaned) | 17/05/2011 |

## 9. GENERAL INFORMATION FROM EFSA

Not discussed.

## 10. EMERGING RISKS

Not discussed.

## 11. MISCELLANEOUS

The WG on flavourings consulted the Panel on the approach, suggested by an applicant, to estimate the residue levels in tissues following the method proposed by Leeman et al. (2007).[8] A preliminary discussion took place and it was agreed that further discussion will be held at the next plenary.

[8] Leeman WR, Van Den Berg KJ, Houben GF, 2007. Transfer of chemicals from feed to animal products: the use of transfer factors in risk assessment. Food Additives and Contaminants, 24, 1-13.