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

## Minutes of the 98th Plenary Meeting

## Held on 10-12 September 2013, Parma

## (Agreed on 8 October 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, Fernando Ramos, Derek Renshaw, Guido Rychen,[1] Maria Saarela, Kristen Sejrsen, John Wallace and Johannes Westendorf.

- **Hearing Experts**

  N/A

- **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, Rosella Brozzi and Loredana Locatelli.

- **Observers**

  N/A

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Patrick van Beelen.

### 2. Adoption of agenda

The agenda was adopted after the deletion of the items “Econase GT (endo-1,3(4)-beta-glucanase) for chickens for fattening and piglets (weaned) (EFSA-Q-2012-00065)”, “Cassia gum for dogs and cats (EFSA-Q-2012-00119)”, “Cassia gum (Galactogum) for dogs and cats (EFSA-Q-2012-00120)”, “Cassia gum for dogs and cats (EFSA-Q-2012-00121)”, “Cassia gum (Diagum™ CS) for cats and dogs (EFSA-Q-2012-00122)”, “L-Methionine feed grade for all animal species (EFSA-Q-2012-00581)” and “Quantum Blue (6-phytase) for laying hens, minor laying poultry species (EFSA-Q-2012-00905)”.

[1] Present only on 10 and 11 September.

## 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[2] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests,[3] 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 97th Plenary meeting held on 9-11 July 2013

The minutes of the 97th Plenary meeting were reviewed and agreed.[4]

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

### 5.1. Amylofeed (endo-1,3(4)-beta-glucanase, endo-1,4-beta-xylanase and alpha-amylase) for piglets (weaned) and young minor porcine species (EFSA-Q-2010-01519)

Not discussed due to lack of time.

### 5.2. Brilliant Black PN for non food-producing animals (EFSA-Q-2010-01526)

The Chair of the working group (WG) presented the question. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Brilliant Black PN as sensory additive for non food-producing animals.

Discussion focussed on the safety of this additive. The opinion will be re-discussed in future Panel meetings.

### 5.3. *Saccharomyces cerevisiae* (NBRC 0203), *Lactobacillus plantarum* (NBRC 3070) and *Lactobacillus casei* (NBRC 3425) for all animal species (EFSA-Q-2011-00390)

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 *Saccharomyces cerevisiae* (NBRC 0203), *Lactobacillus plantarum* (NBRC 3070) and *Lactobacillus casei* (NBRC 3425) as a technological additive for all animal species.

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 irritant to skin/eye and respiratory tract and a skin/respiratory sensitiser. The Panel also concluded that there is no evidence that the additive has the potential to improve the production of silage. Although there was some evidence for an effect on aerobic stability, because of the inherent variability of the additive mix an effective dose could not be established.

The opinion was adopted.[6]

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2 http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
3 http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
4 http://www.efsa.europa.eu/en/events/event/130709-m.pdf
5 During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.
6 http://www.efsa.europa.eu/en/efsajournal/pub/3362.htm

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

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 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 discussed. The Panel concluded that the final product does not raise any safety concern with regard to the genetic modifications. The additive is safe for non-ruminant target species (oral administration to ruminants is best avoided), for consumers and for the environment. The additive is not irritant nor skin sensitiser, but exposure by inhalation is likely. The Panel also concluded that L-tryptophan is efficacious as a supplemented amino acid to maintain or restore the adequate balance of amino acids for animal nutrition.

The opinion was adopted.[7]

### 5.5. 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 three forms of L-lysine are produced by the same genetically modified strain of *Escherichia coli*.

The draft opinion was discussed. The Panel concluded that the final products do not raise any safety concerns with regard to the genetic modifications. The three forms of lysine are considered safe for the target species, consumers and environment, and concerns for users are limited to respiratory sensitisation. The Panel also concluded that the three forms are efficacious.

The opinion was adopted.[8]

### 5.6. 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)

The Chair of the WG presented the question. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Biostrong® 510 (preparation of essential oil of thyme and star anise) as a zootechnical additive for chickens and minor avian species for fattening and rearing to point of lay.

The WG sought guidance from the Panel on how to address the safety of this additive and in general of other additives containing botanical preparations.

7 http://www.efsa.europa.eu/en/efsajournal/pub/3368.htm
8 http://www.efsa.europa.eu/en/efsajournal/pub/3365.htm

**5.7. *Enterococcus faecium* (NCIMB 10415), *Enterococcus faecium* (NCIMB 11181 - DSM 22502), *Enterococcus faecium* (ATCC 53519) and *Enterococcus faecium* (ATCC 55593) for all animal species (EFSA-Q-2012-00080)**

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of four strains of *Enterococcus faecium* (NCIMB 10415, NCIMB 11181 - DSM 22502, ATCC 53519 and ATCC 55593) as technological additives for all animal species.

The draft opinion was discussed. The Panel concluded that the additives are safe for the target species, consumers and environment. In the absence of data these products should be regarded as sin/eye irritants and potential skin/respiratory sensitisers. Two of the strains showed the potential to improve the production of silage, while the other two showed little evidence of a benefit.

The opinion was adopted.[9]

**5.8. L-Threonine, technically pure (ThreAMINO®) for all animal species (EFSA-Q-2012-00118)**

The Chair 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 asked the working group to address some issues that required clarification.

**5.9. Quantum Blue (6-phytase) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor poultry species, piglets (weaned), fattening pigs and sows (EFSA-Q-2012-00693)**

The Chair of the WG presented the question. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Quantum Blue (6-phytase) as a zootechnical additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor poultry species, piglets (weaned), fattening pigs and sows.

The draft opinion was discussed. The Panel concluded that the final product does not raise a safety concern with regard to the genetic modification. The additive is safe for the target species, consumers and environment and it should be considered a respiratory sensitiser. The Panel also concluded that the additive has the potential to be efficacious in the different target species.

The opinion was adopted.[10]

**5.10. Zinc amino acid chelate, hydrate (Availa® Zn) for all animal species (EFSA-Q-2013-00278)**

The rapporteur presented the question and the draft opinion. EFSA was requested to deliver an opinion on the characterisation of the additive based on the additional data submitted by the applicant.

9 http://www.efsa.europa.eu/en/efsajournal/pub/3363.htm
10 http://www.efsa.europa.eu/en/efsajournal/pub/3364.htm

The draft opinion was discussed. The new data on the characterisation of the additive were described in detail. The conclusions on safety and efficacy reached in the previous opinion,[11] as well as recommendations remain unchanged.

The opinion was adopted.[12]

### 5.11. Deccox® (decoquinate) for chickens for fattening (EFSA-Q-2013-00343)

A member of the WG presented the question. This question refers to the modification of the terms of authorisation under Article 13(3) of Regulation (EC) No 1831/2003 of Deccox® (decoquinate) as a coccidiostat for chickens for fattening. The applicant requested the modification of the withdrawal period from three to zero days.

The draft opinion was discussed. The Panel concluded that a zero days withdrawal time does not compromise consumer safety and that the new residues data submitted confirm that no maximum residue limits are considered necessary.

The opinion was adopted.[13]

### 5.12. *Lactobacillus plantarum* (ATCC55058) and *Lactobacillus plantarum* (ATCC55942) (EFSA-Q-2013-00421) and *Pediococcus acidilactici* (CNCM I-3237) for all animal species (EFSA-Q-2013-00436)

Not discussed due to lack of time.

## 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-2013-00681 | Ferric (III) ammonium hexacyanoferrate (II) |
| EFSA-Q-2013-00680 | Natriumhexacyanoferrat(II)-Ferrocyannatrium |
| EFSA-Q-2013-00679 | Potassium hexacyanoferrate(II) |
| EFSA-Q-2013-00677 | L-tryptophan (technically pure) produced using strain AG8012X derived from *Escherichia coli* K-12 |
| EFSA-Q-2013-00678 | Potassium alginate |
| EFSA-Q-2013-00676 | L-threonine (technically pure), produced using strain AG7056X derived from *Escherichia coli* K-12 |
| EFSA-Q-2013-00706 | Salinomycin sodium |
| EFSA-Q-2013-00704 | *Pediococcus acidilactici* (CNCM) ME 18/5M |
| EFSA-Q-2013-00705 | Decoquinate |

11 http://www.efsa.europa.eu/en/efsajournal/pub/2621.htm
12 http://www.efsa.europa.eu/en/efsajournal/pub/3369.htm
13 http://www.efsa.europa.eu/en/efsajournal/pub/3370.htm

## 6.2. Questions received under Regulation (EC) No 178/2002 since the previous meeting

| EFSA-Q-Number | Subject |
|---|---|
| EFSA-Q-2013-00735 | *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237 |
| EFSA-Q-2013-00736 | *Lactobacillus brevis* DSM 23231 |

## 6.3. 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 |
|---|---|---|---|
| 1 | EFSA-Q-2013-00594 | *Clostridium butyricum* MIYAIRI 588 (CBM 588) for turkeys for fattening and turkeys reared for breeding to point of lay | 15/07/2013 |
| 2 | EFSA-Q-2013-00585 | Potassium diformate for pigs for fattening, piglets (weaned), sows for reproduction, chickens for fattening | 16/07/2013 |
| 3 | EFSA-Q-2013-00522 | Diclazuril for guinea fowl | 29/07/2013 |
| 4 | EFSA-Q-2013-00068 | Tertiary-butylhydroquinone (TBHQ) for all animal species | 06/08/2013 |
| 5 | EFSA-Q-2013-00431 | Natural mixture of dolomite plus magnesite and magnesium-phyllosilicates for all animal species | 06/08/2013 |
| 6 | EFSA-Q-2013-00070 | Polyethyleneglycol ester of fatty acids from soya oil for calves | 06/08/2013 |
| 7 | EFSA-Q-2013-00071 | Polyethyleneglycol ester of fatty acids from soya oil for all animal species | 06/08/2013 |
| 8 | EFSA-Q-2013-00528 | Preparation of xylanase and β-glucanase for chickens for fattening, laying hens, turkeys for fattening, piglets (weaned), avian species (game birds, ducks, geese, pigeons, sporting and ornamental birds) including laying birds, chickens reared for laying, turkeys reared for breeding | 27/08/2013 |
| 9 | EFSA-Q-2013-00677 | L-tryptophan (technically pure) produced using strain AG8012X derived from *Escherichia coli* K-12 for all animal species | 03/09/2013 |
| 10 | EFSA-Q-2013-00676 | L-threonine (technically pure), produced using strain AG7056X derived from *Escherichia coli* K-12 for all animal species | 03/09/2013 |

These applications were assigned to the working groups on Microorganisms (#1), Technological additives (#2, #4-7), Coccidiostats (#2), Enzymes (#8), Amino Acids (#9 and #10) and Genetically Modified Microorganisms (#9 and 10).

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

- The Panel was informed that the public consultation on the guidance for the renewal of additives was closed. The comments will be considered by the working group and a new draft of the guidance presented in the next plenary for possible adoption.
- The Panel was informed about two EFSA consultations, one regarding “modern and emerging methodologies for human hazard assessment of chemicals” and another on the “draft guidance on expert knowledge elicitation in food and feed safety risk assessment”.

## 8. Other scientific topics for information and/or discussion

- The Panel was informed about recent notifications on the RASFF regarding the presence of chloramphenicol in food and feed enzyme preparations.
- A short discussion took place on a proposal submitted by some petitioners regarding the duration of tolerance studies in weaned piglets. This issue will be further discussed in a future plenary.

## 9. Any other business

- Not discussed.