# Scientific Panel on Additives and Products or Substances used in Animal Feed

## Minutes of the 110th plenary meeting

## Held on 10-12 March 2015, Parma

## (Agreed on 28 April 2015)

These minutes replace an earlier version following an editorial amendment that does not affect their contents or outcome. To avoid confusion, the original version has been removed from the EFSA website.

### Participants

- **Panel Members:**

  Gabriele Aquilina, Vasileios Bampidis, Maria De Lourdes Bastos, Lucio Guido Costa, Gerhard Flachowsky, Mikolaj Antoni Gralak, Christer Hogstrand,[1] Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Fernando Ramos, Derek Renshaw, Guido Rychen, Maria Saarela, Kristen Sejrsen, Patrick van Beelen, John Wallace and Johannes Westendorf

- **Hearing Experts:** [2]
  - Andrew Chesson[3] (for item 5.3 and 5.9) and Robert Luttik[4] (for item 7.1)
- **European Commission and/or Member States representatives:**
  - N/A
- **EFSA:**
  - **FEED Unit**: Manuela Tiramani, Jaume Galobart, Jaime Aguilera, Lucilla Gregoretti, Gloria López-Gálvez, Oriol Ribó, Jordi Tarrés-Call and Maria Vittoria Vettori
  - **SCER Unit:** Reinhilde Schoonjans[5]
- **Observers**
  - N/A

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

### 2. Adoption of agenda

The agenda was adopted after removal of the item "Aviax 5% (semduramicin sodium) for chickens for fattening (EFSA-Q-2014-00219)".

### 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[6] and the Decision of the Executive Director on Declarations of Interest,[7] EFSA

[1] Present only on 11 and 12 March.
[2] As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf
[3] Present only on 11 and 12 March.
[4] Present only on 12 March.
[5] Present only on 12 March.
[6] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[7] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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 109th Plenary meeting held on 27-29 January 2015

The minutes of the 109th Plenary meeting were reviewed and agreed.[8]

## 5. Scientific outputs submitted for discussion and possible adoption[9]

### 5.1. Chemically defined flavourings from Chemical Group 31 - Aliphatic and aromatic hydrocarbons for all animal species and categories (EFSA-Q-2010-00816)

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of nine compounds from the chemically defined flavourings from the chemical group 31 as sensory additives for all animal species.

The draft opinion was discussed. The Panel could not assess 1,4(8),12-bisabolatriene due to the absence of data on purity. The Panel concluded that the remaining compounds are safe for the target species, consumers and the environment. All compounds should be considered as irritants to skin, eyes and respiratory tract and as skin sensitisers. The Panel also concluded that since they are all used as food flavours, no further demonstration of efficacy is needed.

The opinion was adopted.[10]

### 5.2. Chemically defined flavourings from Chemical Group 05 - Saturated and unsaturated aliphatic secondary alcohols/ketones/ketals/esters with esters containing secondary alcohols. No aromatic or heteroaromatic moiety as a component of an ester or ketal for all animal species and categories (EFSA-Q-2010-01040)

Not discussed due to lack of time.

### 5.3. Ammonium formate, sodium formate and calcium formate for all animal species (EFSA-Q-2011-00424)

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 ammonium formate, sodium formate and calcium formate as technological additives for all animal species.

The draft opinion was discussed. The Panel concluded that calcium formate and sodium formate are safe for the target species, while concerns arise from ammonium formate due to the presence of formamide. The additives are considered safe for the consumer and the environment but are hazardous for users. Although the liquid forms of sodium and ammonium formate were efficacious as preservatives, the solid forms of these additives

[8] http://www.efsa.europa.eu/en/events/event/150127-m.pdf
[9] During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.
[10] http://www.efsa.europa.eu/en/efsajournal/pub/4053.htm

as well as calcium formate did not show a preserving effect. Sodium formate is considered efficacious as silage additive while efficacy of ammonium formate was not demonstrated.

The opinion was adopted.

### 5.4. Copper (cupric acetate monohydrate, basic cupric carbonate monohydrate, cupric chloride, dihydrate, cupric oxide, cupric sulphate, pentahydrate, cupric chelate of amino acids hydrate and cupric chelate of glycine hydrate) for all animal species (EFSA-Q-2011-00741)

The rapporteurs presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of several copper compounds as nutritional additives for all animal species.

The draft opinion was discussed. The Panel concluded that all the copper compounds under application are safe sources of copper for all animal species/categories when used up to maximum EU authorised copper levels in complete feed, but its use in water for drinking is unsafe for sheep and certain breeds of dogs and cats; the simultaneous use of copper compounds via feed and water for drinking should be avoided. These additives are considered safe for the consumer but hazardous for the user. Potential environmental concerns were identified but final conclusions would require additional data/model validation. The Panel also considered that these compounds are an efficacious source of copper for animals.

The opinion was adopted.[11]

### 5.5. Zinc (zinc acetate dehydrate, zinc chloride anhydrous, zinc oxide, zinc sulphate heptahydrate, zinc sulphate monohydrate, zinc chelate of amino acids hydrate and zinc chelate of glycine hydrate for all animal species (EFSA-Q-2011-00845)

The rapporteurs presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of several zinc compounds as nutritional additives for all animal species.

The draft opinion was discussed. The Panel concluded that all the zinc compounds under application are safe sources of copper for all animal species/categories when used up to maximum EU authorised copper levels in complete feed. The simultaneous use of zinc compounds via feed and water for drinking should be avoided. These additives are considered safe for the consumer but hazardous for the user. The use of the additives under application does not pose an immediate concern for the agricultural soil compartment but there is a potential concern related to drainage and the runoff of zinc to surface water. The Panel also considered that these compounds are an efficacious source of copper for animals.

The opinion was adopted.[12]

[11] http://www.efsa.europa.eu/en/efsajournal/pub/4057.htm
[12] http://www.efsa.europa.eu/en/efsajournal/pub/4058.htm

### 5.6. L-lysine monohydrochloride (technically pure) for all animal species (EFSA-Q-2011-00995)

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of L-lysine monohydrochloride as nutritional additives for all animal species.

The draft opinion was discussed. The Panel concluded that the amino acid L-lysine itself is considered safe for target animals, consumers and the environment. However, due to insufficient characterisation of the genetic modification of the production strain, the Panel could not conclude on the safety for target animals, consumers, the user and the environment. Concerns for users arise also from the level of endotoxins present in the product. The Panel considered that the additive is an effective source of L-lysine for animals.

The opinion was adopted.[13]

### 5.7. L-Threonine technically pure for all animal species (EFSA-Q-2012-00117)

The chair of the working group presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of L-threonine technically pure as nutritional additives for all animal species.

The draft opinion was discussed. The Panel concluded that the amino acid L-threonine itself is considered safe for target animals, consumers, the user and the environment. However, due to insufficient characterisation of the genetic modification of the production strain, the Panel could not conclude on the safety for target animals, consumers and the environment. Concerns for users arise also from the level of endotoxins present in the product. The Panel considered that the additive is an effective source of L-threonine for animals.

The opinion was adopted.[14]

### 5.8. Ferrous carbonate for all animal species (EFSA-Q-2012-00495)

Not discussed due to lack of time.

### 5.9. Cibenza® EP150 (preparation of protease, EC 3.4.21.19 and *Bacillus licheniformis*, ATCC 53757) for chickens for fattening, chickens reared for laying, poultry and game birds for fattening and reared for laying excluding laying birds, ornamental birds and sporting birds for fattening and reared for laying excluding laying birds (minor avian species for fattening and to point of lay: ducks, geese, pigeons and other game birds, ornamental and sporting birds) (EFSA-Q-2013-00630)

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 product Cibenza® EP150 (a preparation of protease and *Bacillus licheniformis*, ATCC 53757) as a zootechnical additive for avian species.

[13] http://www.efsa.europa.eu/en/efsajournal/pub/4052.htm
[14] http://www.efsa.europa.eu/en/efsajournal/pub/4051.htm

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumers and the environment. The additive is an eye irritant and should be considered a skin/respiratory sensitiser. The Panel also concluded that the additive is efficacious.

The opinion was adopted.[15]

### 5.10. Formic acid, ammonium formate and sodium formate for all animal species (EFSA-Q-2013-00755)

Not discussed due to lack of time.

### 5.11. Hostazym® C (endo-1.4-beta glucanase) for chickens for fattening, all other birds for fattening and piglets (weaned) (EFSA-Q-2014-00297)

The rapporteur presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety of Hostazym® C (endo-1.4-beta glucanase) as a zootechnical additive based on the additional information submitted by the applicant.

The draft opinion was discussed. Based on the additional information supplied by the applicant and taking into account the previous opinion on the same product, the Panel concluded that Hostazym C is considered safe for target animals and consumers. However, with regards to user safety the previous conclusion that the additive should be considered a potential skin and eye irritant, and a potential skin and respiratory sensitiser applies.

The opinion was adopted.[16]

## 6. New mandates

### 6.1. New applications under Regulation (EC) No 1831/2003

The Commission has forwarded to EFSA the following new application of feed additives seeking authorisation under Regulation (EC) No 1831/2003 since the last Plenary meeting. This application was presented to the Panel, who accepted it:

| EFSA-Q-Number | Subject |
|---|---|
| EFSA-Q-2015-00145 | BIOMIN® BBSH 797 - DSM 11798; Genus nov. species nov. (BIOMIN® BBSH 797) for all avian species |

[15] http://www.efsa.europa.eu/en/efsajournal/pub/4055.htm
[16] http://www.efsa.europa.eu/en/efsajournal/pub/4054.htm

### 6.2. 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-2014-00827 | Fecinor (*Enterococcus faecium* CECT 4515) for piglets (weaned) and chickens for fattening | 25/02/2015 |
| EFSA-Q-2014-00829 | Optiphos® G4000, Optiphos® CT 4000, Optiphos® L8000 (6-phytase EC 3.1.3.26) for pigs for fattening | 25/02/2015 |
| EFSA-Q-2014-00459 | Vermiculite for pigs, poultry, bovines, sheep, goats, rabbits and horses | 04/03/2015 |

These applications were assigned to the respective working groups.

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

### 7.1. Scientific Committee and other Scientific Panels

- The Chair of the Scientific Committee's Environmental risk assessment overarching group presented the three draft opinions regarding overarching elements of environmental risk assessment and asked the Panel to submit comments to these draft opinions.

### 7.2. Working groups

- A member of the Working Group on Colourings provided some feedback on the current status of the evaluation of titanium dioxide as food and feed additive.

### 7.3. EFSA

- The Panel was informed about the info session on feed additives applications that will take place on 5-6 May in Barcelona.

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

Not discussed

## 9. Any Other Business

Not discussed