

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

### Minutes of the 137<sup>th</sup> Plenary meeting

Held on 22-24 January 2019, Parma (Italy)

(Agreed by written procedure on 25 January 2019)

#### Participants

##### ■ Panel Members

Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso<sup>1</sup>, Secundino López Puente<sup>2</sup>, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz<sup>3</sup>, Roberto Villa and Ruud Woutersen.

##### ■ Hearing Experts:

N/A

##### ■ European Commission and/or Member States representatives:

Marta Ponghellini (DG SANTE)

##### ■ EFSA:

FEED Unit: Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini, Elisa Pettenati, Fabiola Pizzo, Konstantinos Sofianidis, Jordi Tarrés-Call, Frank Verdonck and Maria Vittoria Vettori.

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

#### 2. Adoption of agenda

The agenda was adopted after the removal of the topics "L-Tryptophan produced by fermentation with *Escherichia coli* K12 KCCM 80135 for all animal species (EFSA-Q-2017-00542)" and "L-Tryptophan produced by fermentation with *Escherichia coli* K12 KCCM 80152 for all animal species

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<sup>1</sup> Participated via webconference

<sup>2</sup> Participated via webconference

<sup>3</sup> Participated on 23 and 24 January 2019

(EFSA-Q-2017-00693)” and the addition of “Robenz 66G (robenidine hydrochloride) for chickens for fattening and turkeys for fattening (EFSA-Q-2013-00976)”.

### **3. Declarations of Interest of Scientific Panel members**

In accordance with EFSA’s Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present plenary meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

### **4. Report on the written procedures since 136<sup>th</sup> Plenary meeting**

The minutes of the 136<sup>th</sup> Plenary meeting held on 27-29 November 2018 were agreed by written procedure on 5 December 2018.<sup>6</sup>

### **5. Scientific outputs submitted for discussion and/or possible adoption**

#### **5.1. Robenz 66G (robenidine hydrochloride) for chickens for fattening and turkeys for fattening ([EFSA-Q-2013-00976](#))**

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Robenz 66G (robenidine hydrochloride) as a coccidiostat for chickens for fattening and turkeys for fattening.

The draft opinion was discussed, focusing mainly on the characterisation of the additive and its safety and efficacy. The Panel unanimously adopted the opinion.

#### **5.2. Sodium molybdate, dihydrate for sheep ([EFSA-Q-2015-00766](#))**

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of sodium molybdate, dihydrate as a nutritional additive for sheep.

The draft opinion was discussed, focusing mainly on the characterisation of the additive and its safety and efficacy. The Panel unanimously adopted the opinion.

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<sup>4</sup> [Policy on Independence](#)

<sup>5</sup> [Competing Interest Management](#)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/event/feedap181002\\_web\\_m.pdf](http://www.efsa.europa.eu/sites/default/files/event/feedap181002_web_m.pdf)

**5.3. Actisaf® Sc47 (*Saccharomyces cerevisiae* CNCM I-4407) for piglets (weaned), sows, dairy cows for milk production, cattle for fattening ([EFSA-Q-2016-00137](#))**

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Actisaf® Sc47 (*Saccharomyces cerevisiae* CNCM I-4407) as a zootechnical additive for piglets (weaned), sows, dairy cows for milk production, cattle for fattening.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, its safety and its efficacy. The Panel unanimously adopted the opinion.

**5.4. L-Valine for all animal species ([EFSA-Q-2016-00379](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-valine as a nutritional additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, its safety and its efficacy. The Panel unanimously adopted the opinion.

**5.5. Omega-6-fatty acid as octadecadienoic acid (conjugated linoleic acid-methylester) (Lutalin) for pigs for fattening, sows and cows ([EFSA-Q-2016-00859](#))**

EFSA was requested to deliver an opinion on the efficacy of the product Omega-6-fatty acid as octadecadienoic acid (conjugated linoleic acid-methylester) as a nutritional additives for pigs for fattening, sows and cows based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focussed mainly on the efficacy the additive for the target animals. The Panel unanimously adopted the opinion.

**5.6. Typlex® Chelate (ferric tyrosine chelate) for all avian species ([EFSA-Q-2017-00481](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Typlex® Chelate (ferric tyrosine chelate) as a zootechnical additive for all avian species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation and the efficacy of the additive. The Panel unanimously adopted the opinion.

**5.7. L-Tryptophan, technically pure produced by *Escherichia coli* CGMCC 7248 for all animal species ([EFSA-Q-2017-00485](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-tryptophan produced by *Escherichia coli* CGMCC 7248 as a nutritional additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, its safety and its efficacy. The Panel unanimously adopted the opinion.

**5.8. Beltherm MP and Beltherm ML (endo-1,4-beta-xylanase) for piglets (weaned), pigs for fattening and other porcine species ([EFSA-Q-2017-00749](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Beltherm MP and Beltherm ML (endo-1,4-beta-xylanase) as zootechnical additive for piglets (weaned), pigs for fattening and other porcine species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, its safety and its efficacy. The Panel unanimously adopted the opinion.

**5.9. L-Threonine produced by fermentation with *Corynebacterium glutamicum* KCCM 80118 for all animal species ([EFSA-Q-2018-00084](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *L-Threonine* produced by fermentation with *Corynebacterium glutamicum* KCCM 80118 as a nutritional additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, its safety and its efficacy. The Panel unanimously adopted the opinion.

**5.10. Oil of *Origanum vulgare* L. subsp. *Hirtum* for poultry ([EFSA-Q-2018-00121](#))**

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of the product Oil of *Origanum vulgare* L. subsp. *Hirtum* as a sensory additive for poultry.

The draft opinion was discussed. Discussion focussed mainly on the characterisation and on safety of the additive. The opinion will be adopted once the report for the European Union Reference Laboratory (EURL) is received.

#### **5.11. Preparation of algae interspaced bentonite for all animal species ([EFSA-Q-2018-00429](#))**

EFSA was requested to deliver an opinion on the efficacy of the preparation of algae interspaced bentonite as a technological additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focussed on the efficacy of the additive. The Panel unanimously adopted the opinion.

#### **5.12. L-Threonine produced by fermentation with *Corynebacterium glutamicum* KCCM 80117 for all animal species ([EFSA-Q-2018-00506](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-Threonine produced by fermentation with *Corynebacterium glutamicum* KCCM 80117 as a nutritional additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive and its safety and efficacy. The Panel unanimously adopted the opinion.

#### **5.13. Natuphos® E (6-phytase) for chickens for fattening, chickens reared for laying and breeding ([EFSA-Q-2018-00623](#)) )**

This question refers to the request for the modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of Natuphos® E (6-phytase) as a zootechnical additive for chickens for fattening, chickens reared for laying and breeding.

The draft opinion was discussed. Discussion focussed mainly on the efficacy of the additive. The Panel unanimously adopted the opinion.

#### **5.14. Bonvital (*Enterococcus faecium* DSM 7134) for sows for reproduction ([EFSA-Q-2018-00647](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Bonvital (*Enterococcus faecium* DSM 7134) as a zootechnical additive for sows for reproduction.

The draft opinion was discussed. Discussion focussed on the safety of the additive for the target species and its efficacy. The Panel unanimously adopted the opinion.

### **5.15. Beltherm for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and turkeys for breeding purposes ([EFSA-Q-2018-00669](#))**

EFSA was requested to deliver an opinion on the safety and efficacy of the product Beltherm MP and Beltherm BL (endo- 1,4-beta-xylanase) as a zootechnical additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, turkeys for breeding purposes, and minor poultry species based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focussed on the characterisation of the additive, its safety and efficacy. The Panel unanimously adopted the opinion.

### **5.16. Calsporin® (*Bacillus subtilis* C-3102, DSM 15544) for all poultry species ([EFSA-Q-2018-00677](#))**

This question refers to the authorisation under Article 4 and to the modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of Calsporin® (*Bacillus subtilis* C-3102, DSM 15544) as a zootechnical additive for all poultry species.

The draft opinion was discussed. Discussion focussed mainly on the efficacy of the additive. The Panel unanimously adopted the opinion.

## **6. New mandates**

### **6.1. New applications under Regulation (EC) No 1831/2003 since the previous meeting**

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:

EFSA-Q Number	Subject
EFSA-Q-2018-00999	Panavital feed (D-glyceric acid) for broiler chickens
EFSA-Q-2018-00952	Muramidase produced by <i>Trichoderma reesei</i> DSM 32338 for turkeys for fattening, turkeys reared for breeding, chickens reared for breeding and other poultry reared for breeding
EFSA-Q-2018-01040	Avizyme® 1505 (endo-1,4-beta-xylanase (EC 3.2.1.8) derived from <i>Trichoderma reesei</i> , alpha-amylase (EC 3.2.1.1) derived from <i>Bacillus amyloliquefaciens</i> and protease (EC 3.4.21.62) derived from <i>Bacillus subtilis</i> ) for all ducks and all other poultry species (except breeders)

EFSA-Q-2018-01017	L-Methionine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80184 and <i>Escherichia coli</i> K12 KCCM 80096 for all animal species
EFSA-Q-2018-01016	Iron chelate of ethylenediamine (FeEDA) for all animal species
EFSA-Q-2018-01039	Danisco Xylanase 40000 G / Danisco Xylanase 40000 L (endo-1,4-beta-xylanase) for all ducks, all other poultry species (except breeders), piglets (weaned, suckling), pigs for fattening and minor growing porcine species

## 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-2018-00690	<i>Bacillus licheniformis</i> DSM 32457 (Optimize) for all animal species	07/12/2018
EFSA-Q-2018-00762	AveMix® XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for chickens for fattening	20/12/2018
EFSA-Q-2018-00893	Yea-Sacc® ( <i>Saccharomyces cerevisiae</i> CBS 493.94) for horses	19/12/2018

These applications were assigned to the respective working groups.

## 6.3. New questions under Regulation (EC) No 178/2002 since the previous meeting

EFSA-Q-Number	Subject
EFSA-Q-2018-00993	Probiom Forte® ( <i>Bacillus subtilis</i> KCCM 10941P and <i>Bacillus coagulans</i> KCCM 11093P) for laying hens, chickens for fattening and chickens reared for laying
EFSA-Q-2018-00925	Monimax® (monesin sodium and nicarbazin) for turkeys for fattening
EFSA-Q-2018-01022	Sodium formate (E 237) for all animal species

These questions were assigned to the respective working groups.

## 7. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

### 7.1. Scientific Committee

- a) Not discussed

### 7.2. EFSA

- a) The Panel was informed on the technical assistance request received by EFSA from EC that regards the risks posed to humans by a vitamin B<sub>2</sub> produced by a genetically modified strain of *Bacillus subtilis* used as a feed additive ([EFSA-Q-2019-00004](#)).

### **7.3. Working Groups**

- a) The Working group on flavourings asked advice to the Panel regarding the data necessary for the assessment of botanical preparations, particularly concerning the safety for the consumers.

### **7.4. European Commission**

Not discussed

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

- a) The Panel was informed on the next steps with regards to the draft guidance for the assessment of the safety of feed additives for the environment.

## **9. Any other business**

Not discussed