

# SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

## MINUTES OF THE 138<sup>th</sup> FEEDAP PLENARY MEETING

**Parma, 26-28 February 2019**

**(Agreed by written procedure on 04 March 2019)**

### Participants

#### ■ Panel Members:

Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Kos Durjava, Maryline Kouba, Marta López-Alonso,<sup>1</sup> Secundino López Puente,<sup>2</sup> Francesca Marcon,<sup>3</sup> Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz,<sup>4</sup> Roberto Edoardo Villa.

#### ■ Hearing Experts:

Not Applicable

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

Marta Ponghellini

#### ■ EFSA:

Feed Unit: Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Lucilla Gregoretti, Orsolya Holczknecht, Matteo Lorenzo Innocenti, 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. Apologies were received by Ruud Woutersen.

### 2. Adoption of agenda

The agenda was adopted without changes.

<sup>1</sup> Participated via webconference

<sup>2</sup> Participated via webconference

<sup>3</sup> Participated on 26 and 27 February

<sup>4</sup> Participated on 26 and 27 February AM



### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present 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. Agreement of the minutes of the 137<sup>th</sup> FEEDAP Plenary meeting held on 22-24 January 2019.

The minutes of the 137<sup>th</sup> Plenary meeting held on 22-24 January 2019 were agreed by written procedure on 25<sup>th</sup> January 2019.<sup>7</sup>

### 5. Scientific topics for discussion

#### 5.1. Lutein for poultry ([EFSA-Q-2012-00535](#))

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Lutein as a sensory additive for poultry.

The draft opinion was discussed, focusing mainly on the characterisation of the additive and its safety. However, due to lack of time, the discussion was not finalised and will continue in the next plenary meeting.

#### 5.2. Sorbitan monolaurate for all animal species ([EFSA-Q-2013-01025](#))

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Sorbitan monolaurate as technological additive for all animal species.

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

#### 5.3. Hemicell<sup>®</sup>-L (endo-1,4-beta-d-mannanase) for chickens for fattening or reared for laying, turkeys for fattening or reared for breeding and minor poultry species ([EFSA-Q-2016-00087](#), [EFSA-Q-2016-00181](#))

These questions refer to the renewal of the authorisation under Article 14, authorisation under Article 4 and a modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of Hemicell<sup>®</sup>-L (endo-1,4-beta-d-mannanase) as zootechnical additive for chickens for fattening or reared for laying, turkeys for fattening or reared for breeding and minor poultry species.

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

#### 5.4. Chemically defined flavourings from Flavouring Group 03 - Alfa, beta-unsaturated (alkene or alkyne) straight-chain and branched-chain aliphatic primary alcohols/aldehydes/acids, acetals and esters with esters

<sup>5</sup> [Policy on Independence](#)

<sup>6</sup> [Competing Interest Management](#)

<sup>7</sup> <http://www.efsa.europa.eu/sites/default/files/event/190122-m.pdf>



containing alfa, beta-unsaturated alcohol and acetal containing alfa, beta-unsaturated alcohols or aldehydes: hex-2-en-1-ol [02.020], nona-2,6-dien-1-ol [02.049], pent-2-en-1-ol [02.050], non-2(cis)-en-1-ol [02.112], tr-2, cis-6-nonadien-1-ol [02.231], 2-dodecenal [05.037], nona-2(trans),6(cis)-dienal [05.058], nona-2,4-dienal [05.071], trans-2-nonenal [05.072], hex-2(trans)-enal [05.073], 2,4-decadienal [05.081], 2,4-heptadienal, hepta-2,4-dienal [05.084], deca-2(trans),4(trans)-dienal [05.140], dodec-2(trans)-enal [05.144], hept-2(trans)-enal [05.150], non-2-enal [05.171], nona-2(trans),6(trans)-dienal [05.172], undec-2(trans)-enal [05.184], trans-2-octenal [05.190], trans-2-decenal [05.191], tr-2, tr-4-nonadienal [05.194], tr-2, tr-4-undecadienal [05.196], allyl heptanoate [09.097], allyl hexanoate [09.244], hex-2(trans)-enyl acetate [09.394] and hex-2-enyl butyrate [09.396] for all animal species and categories ([EFSA-Q-2016-00344](#))

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of 26 chemically defined flavourings from Flavouring Group 03 as sensory additives for all animal species and categories.

The draft opinion was discussed, focusing mainly on the characterisation of the additives and their safety. The Panel unanimously adopted the opinion.

**5.5. Natuphos® (3-phytase) for piglets (suckling and weaned piglets), pigs for fattening, sows for reproduction, chickens for fattening, chickens reared for laying and breeding, laying hens and breeding hens, ducks for fattening, ducks for breeding and laying, turkeys reared for breeding, turkeys for fattening, ornamental birds, minor avian species, all other poultry for laying and breeding (except ducks) ([EFSA-Q-2016-00376](#))**

This question refers to the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Natuphos® (3-phytase) as zootechnical additive for pigs and poultry.

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

**5.6. L-Tryptophan for all animal species ([EFSA-Q-2016-00380](#))**

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

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

**5.7. Guidance on the assessment of the safety of feed additives for the environment ([EFSA-Q-2016-00400](#))**

This question refers to the self-task of the Panel on the revision of the guidance documents. This guidance document covers the assessment of the safety of feed additives for the environment. The draft guidance was endorsed by the FEEDAP Panel for public consultation on 2 October 2018. Discussion focussed on the modifications introduced in the guidance following the comments received in the public consultation. The Panel unanimously adopted the guidance. The Panel also endorsed the technical report prepared by the FEED Unit regarding the outcome of the public consultation.



**5.8. Bonvital (*Enterococcus faecium* DSM 7134) as a feed additive for weaned piglets and pigs for fattening ([EFSA-Q-2016-00452](#), [EFSA-Q-2016-00450](#))**

This question refers to the renewal under Article 14 of Regulation (EC) No 1831/2003 of Bonvital (*Enterococcus faecium* DSM 7134) as zootechnical additive for weaned piglets and pigs 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.

**5.9. PHYZYME® XP 5000 G, PHYZYME® XP 5000 L (6-phytase) weaned piglets, pigs for fattening, sows for reproduction, chickens for fattening, laying hens, turkeys for fattening and ducks for fattening ([EFSA-Q-2016-00559](#))**

Not discussed due to lack of time.

**5.10. L-Lysine monohydrochloride and L-lysine sulphate from *Corynebacterium glutamicum* CCTCC M 2015595 for all animal species ([EFSA-Q-2016-00574](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-lysine monohydrochloride and L-lysine sulphate from *Corynebacterium glutamicum* CCTCC M 2015595 as nutritional additive for all animal species.

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

**5.11. L-Arginine for all animal species ([EFSA-Q-2016-00783](#))**

Not discussed due to lack of time.

**5.12. Natugrain® Wheat TS (endo-1,4-beta-xylanase) for turkeys for fattening, chickens for fattening and ducks, turkeys reared for breeding, ornamental birds, minor avian species except ducks and laying birds ([EFSA-Q-2017-00025](#))**

This question refers to the renewal under Article 14 of Regulation (EC) No 1831/2003 of Natugrain® Wheat TS (endo-1,4-beta-xylanase) as zootechnical additive for turkeys for fattening, chickens for fattening and ducks, turkeys reared for breeding, ornamental birds, minor avian species except ducks and laying birds.

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

**5.13. Probiotic Lactina® (*Enterococcus faecium* NBIMCC 8270, *Lactobacillus acidophilus* NBIMCC 8242, *Lactobacillus helveticus* NBIMCC 8269, *Lactobacillus delbrueckii* ssp. *lactis* NBIMCC 8250, *Lactobacillus delbrueckii* ssp. *bulgaricus* NBIMCC 8244 and *Streptococcus thermophilus* NBIMCC 8253) for chickens for fattening, rabbits (suckling and weaned) ([EFSA-Q-2017-00051](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Probiotic Lactina® as a zootechnical additive for chickens for fattening and rabbits (suckling and weaned).

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



**5.14. Cinergy® Life B3 HiCon (*Bacillus amyloliquefaciens* NRRL B-50508, *B. amyloliquefaciens* NRRL B-50509 and *Bacillus subtilis* NRRL B-50510) for pigs for fattening and minor porcine species ([EFSA-Q-2017-00746](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Cinergy® Life B3 HiCon as a zootechnical additive for pigs for fattening and minor porcine species.

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

**5.15. Levucell SC 20, 10 ME, 10 ME Titan (*Saccharomyces cerevisiae* CNCM I-1077) for lambs and horses ([EFSA-Q-2018-00083](#))**

This question refers to the renewal under Article 14 of Regulation (EC) No 1831/2003 of Levucell SC (*Saccharomyces cerevisiae* CNCM I-1077) as zootechnical additive for lambs and horses.

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

**5.16. 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 Oil of *Origanum vulgare* L. subsp. *Hirtum* as sensory additive for poultry.

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

**5.17. Chemically defined flavourings for use in cats and dogs from different Chemical Groups ([EFSA-Q-2018-00123](#))**

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of eight chemically defined flavourings from different chemical groups as sensory additives for use in cats and dogs.

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

**5.18. L-Leucine produced using strain NITE BP-02351 for all animal species ([EFSA-Q-2018-00548](#))**

Not discussed due to lack of time.

**5.19. Probion Forte® (*Bacillus subtilis* KCCM 10941P and *Bacillus coagulans* KCCM 11093P) for laying hens, chickens for fattening and chickens reared for laying ([EFSA-Q-2018-00993](#))**

EFSA was requested to deliver an opinion on the safety and efficacy of Probion Forte® as a zootechnical additive for laying hens, chickens for fattening and chickens reared for laying based on the additional information submitted by the applicant.

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



## 5.20. Sodium formate (E 237) for all animal species ([EFSA-Q-2018-01022](#))

EFSA was requested to deliver an opinion on the efficacy of sodium formate when used as a technological additive based on the additional information submitted by the applicant.

The draft opinion was discussed, focusing 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-2019-00059	Copper chelate of Ethylenediamine (CuEDA) for all animal species
EFSA-Q-2019-00037	MSG (monosodium L-glutamate) produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80188 for all animal species
EFSA-Q-2019-00041	L-Cysteine hydrochloride monohydrate by fermentation with <i>Escherichia coli</i> KCCM 80109 and <i>Escherichia coli</i> KCCM 80197 for all animal species
EFSA-Q-2019-00042	Natuphos® E (6-phytase) for laying hens, minor poultry and other avian species for laying
EFSA-Q-2019-00040	IMP (disodium 5'-inosinate) produced by fermentation with <i>Corynebacterium ammoniagenes</i> KCCM 80161 for all animal species
EFSA-Q-2019-00036	Dry grape extract 60-20 for cats and dogs

### 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-2010-01516	Botanically defined flavourings from Botanical Group 18 - Gymnosperms (Coniferales, Ginkgoales) for all animal species and categories	11/02/2019
EFSA-Q-2018-00824	ECONASE® XT (endo-1,4-beta-xylanase) for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkey reared for breeding	25/01/2019
EFSA-Q-2018-00815	Gellan gum for cats and dogs	18/01/2019
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	16/01/2019
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	11/02/2019





	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	07/02/2019
EFSA-Q-2018-01016	Iron chelate of Ethylenediamine (FeEDA) for all animal species	07/02/2019
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	11/02/2019

These applications were assigned to the respective working groups, when relevant.

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

EFSA-Q-Number	Subject
EFSA-Q-2019-00079	ZM16 ( <i>Bacillus amyloliquefaciens</i> DSM 25840) for weaned piglets and weaned minor porcine species
EFSA-Q-2019-00048	Erythrosine (E 127) for ornamental fish, cats and dogs
EFSA-Q-2019-00051	<i>Saccharomyces cerevisiae</i> NBRC 0203, <i>Lactobacillus plantarum</i> NBRC 3070 and <i>Lactobacillus casei</i> NBRC 3425 (EM Silage) for all animal species
EFSA-Q-2019-00035	Cygro® 10G (Maduramicin ammonium) for turkeys

These questions were assigned to the respective working groups, when relevant.

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

### 7.1. Scientific Committee

The Chair of the Panel reported on the last meeting of the Scientific Committee, specially on the Open Food Tox database.<sup>8</sup>

### 7.2. EFSA

- The Panel was informed on the publication of the EFSA statement on the risk posed to humans vitamin B<sub>2</sub> produced by a genetically modified strain *Bacillus subtilis* used as a feed additive (EFSA-Q-2019-00004).<sup>9</sup>
- The Feed unit will launch a procurement for an intensive training to the unit's scientific staff.<sup>10</sup>

<sup>8</sup> <https://www.efsa.europa.eu/en/microstrategy/openfoodtox>

<sup>9</sup> [http://www.efsa.europa.eu/sites/default/files/scientific\\_output/ON-5615.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/ON-5615.pdf)

<sup>10</sup> <https://www.efsa.europa.eu/en/consultations/call/190222>



### **7.3. Working Groups**

Not discussed

### **7.4. European Commission**

Not discussed

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

### **8.1. Self-task mandate on the update of the guidance on renewal of the authorisation of feed additives**

The Panel discussed about the need to revise and update the guidance on the renewal of the authorisation of feed additives. The Panel agreed to request the Executive Director for the endorsement of this self-task. A specific working group may be established for this task.

## **9. Any Other Business**

### **9.1. Dates for plenary meetings for 2020**

The Panel agreed on the dates for the plenary meetings for 2020: 28-30 January, 17-19 March, 12-14 May, 30 June – 2 July, 29 September – 1 October and 17-19 November