



FEED UNIT

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

MINUTES OF THE 140th FEEDAP PLENARY MEETING

Parma, 14-16 May 2019

(Agreed by written procedure on 20 May 2019)

Participants

Panel Members:

Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Kos Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente¹, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos,² Yolanda Sanz, Roberto Villa and Ruud Woutersen.

Hearing Experts:

Not Applicable

European Commission and/or Member States representatives:

Marta Ponghellini (DG SANTE)

EFSA:

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

TS Unit: Claudia Paoletti³ and Samantha Carapezzi⁴

Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

Participated via webconference

Participated via webconference on 14 and 16 May

Participated on 14 May for Item 7.2

⁴ Participated on 14 May for Item 7.2





2. Adoption of agenda

The agenda was adopted after the removal of the items "Macleaya cordata extract (Sangrovit) for all animal species (EFSA-Q-2010-01066)" for which the application has been withdrawn and "Mugwort tincture for all animal species (EFSA-Q-2011-00181)" for which the EURL report has not yet been received.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, 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 139th FEEDAP Plenary meeting held on 2-4 April 2019, Parma

The minutes of the 139th FEEDAP Plenary meeting were agreed by written procedure on 9 April 2019⁷.

5. Scientific topic(s) for discussion

5.1. Botanically defined flavourings from Botanical Group 09 - Zingiberales for all animal species and categories: cardamom oil from *Elettaria cardamomum* (L.) Maton (<u>EFSA-Q-2010-01293</u>)

This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Botanically defined flavourings from Botanical Group 09 – Zingiberales: cardamom oil from *Elettaria cardamomum*, as a sensory additive for all species and categories.

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

5.2. Great mullein tincture for all animal species (EFSA-Q-2011-00146)

Not discussed due to lack of time

5.3. L-Arginine for all animal species (EFSA-Q-2016-00783)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of L-Arginine as nutritional additive for all animal species.

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

6 Competing Interest Management

2

⁵ <u>Policy on Independence</u>

https://www.efsa.europa.eu/sites/default/files/event/190402-min.pdf





5.4. Aluminosilicate of sodium, potassium, calcium and magnesium for pigs (EFSA-Q-2017-00503)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the product aluminosilicate of sodium, potassium, calcium and magnesium as a technological additive for pigs.

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

5.5. Vevovitall® (benzoic acid) for pigs for fattening (EFSA-Q-2017-00648)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Vevovitall® (benzoic acid) as a zootechnical additive for pigs for fattening.

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

5.6. Copper chelates of lysine and glutamic acid (ProPath Cu) for all animal species (EFSA-Q-2018-00011)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Copper chelates of lysine and glutamic acid (ProPath Cu) as a 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. Biomin® DC-P (preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol) for chickens for fattening, chickens reared for laying, minor avian species other than laying species (<u>EFSA-Q-2018-00418</u>)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Biomin® DC-P (preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol) as a zootechnical additives for chickens for fattening, chickens reared for laying, minor avian species up to the point of lay.

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

5.8. L-Histidine monohydrochloride monohydrate (feed grade) produced by fermentation with *Corynebacterium glutamicum* KCCM 80172 for all animal species (EFSA-Q-2018-00438)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-Histidine monohydrochloride monohydrate produced by fermentation with Corynebacterium glutamicum KCCM 80172 as a nutritional additive for all animal species.

The draft opinion was partially discussed focusing mainly on the characterisation of the additive and its safety. The discussion will continue in the next plenary.





5.9. L-Tryptophan produced by fermentation with *Corynebacterium glutamicum* KCCM 80176 for all animal species (<u>EFSA-Q-2018-00451</u>)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-Tryptophan produced by fermentation with *Corynebacterium glutamicum* KCCM 80176 as a 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.

5.10. Biosprint® (Saccharomyces cerevisiae MUCL 39885) for sows (EFSA-Q-2018-00474)

This question refers to the renewal of the authorisation under Article 14 of a Biosprint® (Saccharomyces cerevisiae MUCL 39885) as a zootechnical additive for sows.

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

5.11. L-Histidine monohydrochloride monohydrate produced by fermentation with *Corynebacterium glutamicum* KCCM 80179 for all animal species (EFSA-Q-2018-00547)

Not discussed due to lack of time

5.12. Bacillus subtilis DSM 28343 for pigs for fattening (EFSA-Q-2018-00584)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Bacillus subtilis* DSM 28343 as a zootechnical additive for pigs for fattening.

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

5.13. Levucell SC® (Saccharomyces cerevisiae CNCM I-1077) for calves and other (pseudo)ruminants species at the corresponding developmental stage (EFSA-Q-2018-00630)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Levucell SC (*Saccharomyces cerevisiae* CNCM I-1077) as zootechnical additive for calves and minor ruminant species at the corresponding developmental stage.

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

5.14. BioPlus[®] 2B (*Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750) for turkeys for fattening (<u>EFSA-Q-2018-00668</u>)

This question refers to modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of BioPlus® 2B (*Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750) as a zootechnical additive for turkeys for fattening.

The draft opinion was discussed focusing mainly on the compatibility of the additive with certain coccidiostats and formic acid. The Panel unanimously adopted the opinion.

5.15. Fra® Octazyme C Dry (alpha-galactosidase, alpha-amylase, endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, mannan-endo-1,4-beta-





mannosidase, pectinase, protease, endo-1,4-beta-xylanase) for chickens for fattening and weaned piglets (<u>EFSA-Q-2018-00798</u>)

EFSA has been asked to deliver an opinion on the safety and efficacy Fra® Octazyme C Dry (alpha-galactosidase, alpha-amylase, endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, mannan-endo-1,4-beta-mannosidase, pectinase, protease, endo-1,4-beta-xylanase) as a zootechnical additive for chickens for fattening and weaned piglets based on the new data provided by the applicant.

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

6. New mandates

6.1. New Applications under Regulation (EC) 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-2019-00219	BIOSPRINT® (Saccharomyces cerevisiae MUCL 39885) for horses and dairy cows
EFSA-Q-2019-00301	Sepiolite and diatomaceous earth for all terrestrial species
EFSA-Q-2019-00312	APSA PHYTAFEED® 20,000 GR, APSA PHYTAFEED® 20,000 L (6-phytase) for pigs for fattening
EFSA-Q-2019-00293	L-Isoleucine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80189 for all animal species
EFSA-Q-2019-00303	OptiPhos® PLUS (6-phytase) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening, minor poultry species reared for breeding and ornamental birds
EFSA-Q-2019-00260	Formi LHS (potassium diformate) for piglets (weaned), pigs for fattening

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-2019-00104	25-hydroxycholecalciferol for pigs and poultry	02/04/2019
EFSA-Q-2019-00117	GalliPro® Fit (Bacillus subtilis DSM 32324, Bacillus subtilis DSM 32325 and Bacillus amyloliquefaciens DSM 25840) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor poultry species	08/04/2019
EFSA-Q-2019-00154	AviPlus® (preparation of sorbic acid, citric acid, thymol and	25/04/2019





	vanillin) for turkeys for fattening and turkeys reared for breeding	
EFSA-Q-2019-00155	Nutrase P (6-phytase) for chickens for fattening, other poultry for fattening, reared for laying and ornamental birds	02/04/2019
EFSA-Q-2019-00157	AviPlus® (preparation of sorbic acid, citric acid, thymol and vanillin) for suckling piglets	25/04/2019
EFSA-Q-2019-00173	E460 Microcrystalline cellulose for all animal species	26/04/2019
EFSA-Q-2019-00179	E466 Carboxymethyl cellulose for all animal species	26/04/2019
EFSA-Q-2019-00180	Lactobacillus buchneri DSM 29026 for all animal species	25/04/2019
EFSA-Q-2019-00181	E464 Hydroxypropyl methyl cellulose for all animal species	26/04/2019
EFSA-Q-2019-00182	E463 Hydroxypropyl cellulose for all animal species	26/04/2019
EFSA-Q-2019-00183	E461 Methyl cellulose for all animal species	26/04/2019
EFSA-Q-2019-00188	APSA PHYTAFEED® 20,000 GR, APSA PHYTAFEED® 20,000 L (6-phytase) for turkey for fattening, turkey reared for breeding and minor poultry species	03/05/2019
EFSA-Q-2019-00192	APSA PHYTAFEED® 20,000 GR, APSA PHYTAFEED® 20,000 L (6-phytase) for suckling piglets, weaned piglets and other minor growing porcine species	03/05/2019
EFSA-Q-2019-00194	L-Lysine sulphate produced by fermentation with Corynebacterium glutamicum KFCC 11043 for all animal species	07/05/2019

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

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

EFSA-Q-Number	Subject
EFSA-Q-2019-00217	EB15 (<i>Bacillus subtilis</i> DSM 25841) for piglets (weaned) and weaned minor porcine species
EFSA-Q-2019-00253	Monimax® (monesin sodium and nicarbazin) for chickens for fattening, chickens reared for laying
EFSA-Q-2019-00261	Bacillus subtilis DSM 28343 for calves for rearing

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

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

7.1. Scientific Committee/Scientific Panels

Not discussed





7.2. EFSA

The Panel was informed on the update of Regulation (EC) No 178/2002 and the measures that are being implemented in EFSA to adapt to these changes.

7.3. European Commission

Not discussed

8. Other scientific topics for information/or discussion

- a) The Panel was informed on the ongoing activities with regards the use of the whole genome sequence analysis for the characterisation of microorganisms used as feed additives or as production strains.
- b) A preliminary discussion took place on the main aspects that need to be updated on the guidance on the renewal of authorisations for feed additives.

9. Any other business

Not discussed