



FEED UNIT

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

MINUTES OF THE 141st FEEDAP PLENARY MEETING

Parma, 02-04 July 2019

(Agreed by written procedure on 11 July 2019)

Participants

■ Panel Members:

Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Kos Durjava, Maryline Kouba, Marta López-Alonso¹, Secundino López Puente², Baltasar Mayo³, Alena Pechová, Mariana Petkova, Yolanda Sanz, Roberto Villa and Ruud Woutersen.

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Marta Ponghellini (DG SANTE); Christoph von Holst (EURL)

■ EFSA:

Feed Unit: Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Lucilla Gregorette, 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.

■ Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Francesca Marcon and Fernando Ramos.

¹ Participated via webconference

² Participated via webconference

³ Participated via webconference on the 2 July



2. Adoption of agenda

The agenda was adopted after deletion of "Mugwort tincture for all animal species (EFSA-Q-2011-00181)" for which the EURL report has not yet been received and "L-Glutamine produced using strain *Corynebacterium glutamicum* NITE BP02524 for all animal species (EFSA-Q-2018-00693)" and the addition of "*Bacillus subtilis* DSM 28343 for calves for rearing (EFSA-Q-2019-00261)" and "Natural essential oil from *Origanum vulgare* L. ssp. *hirtum* var. Vulkan (DOS 00001) for all animal species (EFSA-Q-2019-00314)".

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Panel 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 140th FEEDAP Plenary meeting held on 14-16 May 2019, Parma

The minutes of the 140th FEEDAP Plenary meeting were agreed by written procedure on 20 May 2019⁶.

5. Scientific topic(s) for discussion

5.1. Great mullein tincture for all animal species ([EFSA-Q-2011-00146](#))

Not discussed due to lack of time.

5.2. Maxiban® G160 (narasin 80 g activity/kg and nicarbazin 80 g/kg) for chickens for fattening ([EFSA-Q-2015-00032](#))

This question refers to modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of Maxiban® G160 (narasin 80 g/kg and nicarbazin 80 g/kg) as a coccidiostat for chickens for fattening.

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

5.3. Preparation of 3-phytase (EC 3.1.3.8) produced by *Komagataella pastoris* ([EFSA-Q-2017-00447](#)) for pigs for fattening and minor porcine species

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of a preparation of 3-phytase produced by *Komagataella pastoris* (CECT 13094) as a zootechnical additive for pigs for fattening and minor growing porcine species.

⁴ [Policy on Independence](#)

⁵ [Competing Interest Management](#)

⁶ <http://www.efsa.europa.eu/sites/default/files/event/190514-1-m.pdf>



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

5.4. Sodium selenate for ruminants ([EFSA-Q-2017-00644](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of sodium selenate as a nutritional additive for all ruminants.

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. Zinc chelates of lysine and glutamic acid (ProPath Zn) for all animal species ([EFSA-Q-2018-00012](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Zinc chelates of lysine and glutamic acid (ProPath Zn) 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.

5.6. Oregano oil for all animal species ([EFSA-Q-2018-00122](#))

Not discussed due to lack of time.

5.7. Belfeed B MP/ML (endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG S-15136) for sows in order to have benefit in piglets and all porcine species and life stages ([EFSA-Q-2018-00253](#))

Not discussed due to lack of time.

5.8. Iron chelates of lysine and glutamic acid (ProPath Fe) for all animal species ([EFSA-Q-2018-00255](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Iron chelates of lysine and glutamic acid (ProPath Fe) 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.

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



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

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 80179 as a nutritional and sensory 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.

5.11. Ronozyme® WX (CT)/Ronozyme® WX (L) (endo-1,4-beta-xylanase) for sows for reproduction ([EFSA-Q-2018-00622](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Ronozyme® WX (CT)/(L) (endo-1,4-beta-xylanase) as a zootechnical additive for sows for reproduction.

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

5.12. *Bacillus licheniformis* DSM 32457 (Optimize) for all animal species ([EFSA-Q-2018-00690](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Bacillus licheniformis* DSM 32457 as a 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.

5.13. L-Histidine monohydrochloride monohydrate using *Escherichia coli* NITE BP-02526 for all animal species ([EFSA-Q-2018-00782](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-Histidine monohydrochloride monohydrate using *Escherichia coli* NITE BP02526 as nutritional and sensory additive for all animal species.

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

5.14. Natuphos® E (6-phytase) for laying hens, minor poultry and other avian species for laying ([EFSA-Q-2019-00042](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Natuphos® E (6-phytase) as a zootechnical additive for laying hens, minor poultry and other avian species for laying.

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

5.15. Bergazym® P 100 (endo-1,4-beta-xylanase) for other birds for fattening, ornamental birds and other growing suidae ([EFSA-Q-2019-00097](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Bergazym® P 100 (endo-1,4-beta-xylanase) as a zootechnical additive for other birds for fattening, ornamental birds and other growing suidae.



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

5.16. AviPlus® (preparation of sorbic acid, citric acid, thymol and vanillin) for turkeys for fattening and turkeys reared for breeding and suckling piglets (EFSA-Q-2019-00154 and EFSA-Q-2019-00157)

These questions refer to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of AviPlus® (preparation of sorbic acid, citric acid, thymol and vanillin) as a zootechnical additive for turkeys for fattening and turkeys reared for breeding and suckling piglets.

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

5.17. *Bacillus subtilis* DSM 28343 for calves for rearing (EFSA-Q-2019-00261)

EFSA has been asked to deliver an opinion on the efficacy of *Bacillus subtilis* DSM 28343 as a zootechnical additive for calves for rearing based on the new data provided by the applicant.

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

5.18. Natural essential oil from *Origanum vulgare* L. ssp. *hirtum* var. Vulkan (DOS 00001) for all animal species (EFSA-Q-2019-00314)

EFSA has been asked to deliver an opinion on the safety of *Origanum vulgare* L. ssp. *hirtum* var. Vulkan as a sensory additive for all animal species based on the new data provided by the applicant.

The draft opinion was discussed focusing on the safety 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-2019-00411	L-Lysine monohydrochloride/Concentrated liquid L-Lysine/L-Lysine sulphate produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM80183 for all animal species
EFSA-Q-2019-00410	<i>Bacillus subtilis</i> PB6 (<i>Bacillus subtilis</i> ATCC PTA-6737) for chickens for fattening, chickens reared for laying and minor poultry species (except for laying purpose)
EFSA-Q-2019-00313	TechnoSpore (<i>Bacillus coagulans</i> DSM 32016) for piglets (suckling and weaned), other growing suidae, chickens for fattening, other poultry for fattening and ornamental birds
EFSA-Q-2019-00332	L-cystine (not less than: 98% L-cystine on dry matter basis) using strain NITE BP-02525 for all animal species



EFSA-Q-2019-00333	FINASE® EC (6-phytase) for pigs other than sows, sows, poultry for fattening and breeding other than turkeys for fattening, poultry for laying and turkeys
EFSA-Q-2019-00331	L-lysine monohydrochloride for all animal species
EFSA-Q-2019-00330	ECONASE® XT (endo-1,4-beta-xylanase) for piglets (weaned), pigs for fattening, chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding and minor poultry species
EFSA-Q-2019-00362	Manganese chelate of hydroxy analogue of methionine (MINTREX® Mn) for all animal species
EFSA-Q-2019-00358	Copper chelate of hydroxy analogue of methionine (MINTREX® Cu) for all animal species
EFSA-Q-2019-00360	Zinc chelate of hydroxy analogue of methionine (MINTREX® Zn) for all animal species
EFSA-Q-2019-00361	L-isoleucine (minimum 93.4% of L-isoleucine expressed on dry matter) for all animal species
EFSA-Q-2019-00334	Montmorillonite-Illite (1g557) for all animal species
EFSA-Q-2019-00370	Calsporin® (<i>Bacillus subtilis</i> C-3102, DSM 15544) for piglets (weaned)
EFSA-Q-2019-00369	<i>Pediococcus pentosaceus</i> DSM 16244 for all animal 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-2010-01286	Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales: Dill herb oil, Dill tincture, Dong quai tincture, Celery seed oil, Celery tincture, Hares ear tincture, Caraway seed oil, Coriander oil, Cumin oil, Taiga root extract (sb), Taiga root tincture, Fennel oil, Fennel tincture, Common ivy extract (sb), Ginseng tincture, Parsley oil, Parsley tincture, Anise oil, Anise tincture, Ajowan oil, Ferula Assa-foetida oil, Anise star oil, Anise star tincture, Anise star terpenes, Omicha tincture for all animal species	24/06/2019
EFSA-Q-2019-00215	Caramel colours E150b, E150c and E150d for all animal species	16/05/2019
EFSA-Q-2019-00219	BIOSPRINT® (<i>Saccharomyces cerevisiae</i> MUCL 39885) for horses and dairy cows	21/06/2019
EFSA-Q-2019-00112	Formi LHS (potassium diformate) for sows for reproduction	05/06/2019
EFSA-Q-2019-00156	RONOZYME® ProAct (serine protease EC 3.4.21.- produced by <i>Bacillus licheniformis</i> DSM 19670) for chickens for fattening	11/06/2019
EFSA-Q-2019-00301	Sepiolite and diatomaceous earth for all terrestrial species	18/06/2019
EFSA-Q-2019-00293	L-Isoleucine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80189 for all animal species	05/06/2019



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-2019-00365	<i>Lactococcus lactis</i> NCIMB 30160 for all animal species
EFSA-Q-2019-00319	Vitamin B ₁₂ produced by <i>Ensifer adhaerens</i> SCM 2034 for all animal species
EFSA-Q-2019-00371	Butylated hydroxy anisole (BHA) for all animal species
EFSA-Q-2019-00364	Lactic acid and calcium lactate for all animal species
EFSA-Q-2019-00314	Natural essential oil from <i>Origanum vulgare</i> L. ssp. <i>hirtum</i> var. Vulkan (DOS 00001) for all animal species
EFSA-Q-2019-00380	LANCER (lanthanide-citrate) for weaned piglets

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

The Chair of the Panel informed on the main topics discussed during the last plenary of the Scientific Committee, in particular:

- [OpenFoodTox](#): EFSA's chemical hazards database
- Risk evaluation of chemical contaminants in food in the context of RASFF notifications: Rapid Assessment of Contaminant Exposure tool ([RACE](#))

7.2. EFSA

- The Panel was informed on the meeting with stakeholders which took place on 19 June in Brussels to get input on the update of the guidance on renewal and on the upcoming [FEED additives info session](#) that will take place on 14-15 November in Parma.
- The Panel was also informed on the initial meeting of the WG that deals with the Request for an EFSA scientific opinion as regards specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed (EFSA-2019-00221).

7.3. European Commission

The EC representative informed the Panel about the setting of a Commission Expert Group in the area of animal nutrition.



8. Other scientific topics for information/or discussion

- a) The Panel was presented the technical report of EFSA on “Animal dietary exposure: overview of current approaches used at EFSA” which summarises the approaches taken in the different areas of work of EFSA on the assessment of animal dietary exposure.
- b) The Panel was informed on outcome of the *ad hoc* meeting organised by EFSA on 24th June with industry representatives on smoke flavourings and flavourings other than flavouring substances for use in food and feed regarding the update on recent scientific requirements for the genotoxicity assessment of chemical mixtures.

9. Any other business

The Panel agreed to change the date of the next plenary, which will not be held on 17-19 September but on 4 October (AM) and 7 October (PM) via webconference.