

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

Minutes of the 135th Plenary meeting

Held on 2-4 October 2018, Parma (Italy)

(Agreed by written procedure on 8 October 2018)

Participants

■ Panel Members

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

■ Hearing Experts:

N/A

■ European Commission and/or Member States representatives:

Marta Ponghellini (DG SANTE)

Christoph von Holst (JRC)²

■ EFSA:

FEED Unit: Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Lucilla Gregoret, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Niovi Kordali, Paola Manini, Jordi Tarrés-Call, Manuela Tiramani and Maria Vittoria Vettori.

REPRO HoD: Guilhem de Seze³

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Yolanda Sanz.

¹ Participated via webconference

² Participated only on 3 October.

³ Participated only on 3 October for point 7.1.a

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declarations of Interest. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process. Additionally, no interests were declared at the Oral Declaration of Interest made at the beginning of this meeting.

4. Report on the written procedures since 134th Plenary meeting

The minutes of the 134nd Plenary meeting held on 4-5 July 2018 were agreed by written procedure on 9 July 2018.⁶

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

5.1. Monimax (monensin sodium and nicarbazin) for chickens for fattening, chickens reared for laying (EFSA-Q-2012-00791)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Monimax (monensin sodium and nicarbazin) as a coccidiostat for chickens for fattening and chickens reared for laying.

The draft opinion was discussed, focusing mainly on the characterisation of the additive and its safety for the target species, consumer, user and environment and on its efficacy. The Panel unanimously adopted the opinion.

5.2. Monteban[®] G100 (narasin) for chickens for fattening (EFSA-Q-2013-00767)

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Monteban[®] G100 (narasin) as a coccidiostat for chickens for fattening.

The draft opinion was discussed, focusing mainly on the characterisation of the additive and its safety for the target species, consumer, user and environment and on its efficacy. The Panel unanimously adopted the opinion.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁶ http://www.efsa.europa.eu/sites/default/files/event/180703_1_m.pdf

5.3. Monteban® G100 (narasin) for ducks ([EFSA-Q-2015-00033](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Monteban® G100 as a coccidiostat for ducks.

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

5.4. 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 presented in detail. The draft guidance was endorsed for public consultation.

5.5. 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. The Panel identified some issues that required clarifications and asked the Working Group (WG) to provide a revised opinion in the next plenary.

5.6. L-Lysine monohydrochloride and concentrated liquid L-lysine for all animal species ([EFSA-Q-2017-00501](#))

Not discussed due to lack of time.

5.7. L-Threonine for all animal species ([EFSA-Q-2017-00609](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-threonine 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. The Panel unanimously adopted the opinion.

5.8. Extract from super critical carbon dioxide extraction of *Humulus lupulus* L. flos containing 40% beta acids with propylene glycol for all animal species ([EFSA-Q-2017-00662](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of an extract from super critical carbon dioxide extraction of *Humulus lupulus* as a sensory additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation and on the safety for the target species, consumer and user. The Panel unanimously adopted the opinion.

5.9. Bergazym® P100 (endo-1,4-beta-xylanase) for chickens for fattening and weaned piglets ([EFSA-Q-2017-00682](#))

EFSA was requested to deliver an opinion on the efficacy of Bergazym® P100 (endo-1,4-beta-xylanase) as a zootechnical additive for chickens for fattening and weaned piglets 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.

5.10. Hostazym® X (endo-1,4-beta-xylanase) as a feed additive for sows ([EFSA-Q-2017-00747](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Hostazym® X (endo-1,4-beta-xylanase) as a zootechnical additive for sows in order to have benefits in piglets.

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

5.11. *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323 for all animal species ([EFSA-Q-2018-00287](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323 as a technological additive for all animal species.

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

5.12. Zinc chelate of methionine hydrate (BIOMET Zn) for all animal species [\(EFSA-Q-2018-00307\)](#)

EFSA was requested to deliver an opinion on the safety of Zinc chelate of methionine hydrate as a nutritional additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focussed on the safety for the target species. 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-2018-00680	Lemon extract for all animal species
EFSA-Q-2018-00616	Rosemary extract for all animal species
EFSA-Q-2018-00617	<i>Sus scrofa</i> (extract from defatted porcine pancreatic glands) for cats and dogs and other carnivorous and omnivorous companion animals such as ferrets
EFSA-Q-2018-00621	Olive extract, olive leaf extract (<i>Olea europaea</i> L.) for all animal species
EFSA-Q-2018-00516	PHYZYME® XP 10000 TPT, PHYZYME® XP 10000 L (6-phytase) for all avian species and all swine species
EFSA-Q-2018-00545	L-Tryptophan produced by fermentation with <i>Escherichia coli</i> KCCM 10534 (L-Tryptophan feed grade) for all animal species
EFSA-Q-2018-00546	L-Histidine monohydrochloride monohydrate for other fin fish
EFSA-Q-2018-00547	L-Histidine monohydrochloride monohydrate produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80179 (L-histidine monohydrochloride monohydrate feed grade) for all animal species
EFSA-Q-2018-00548	L-Leucine produced using strain NITE BP-02351 for all animal species
EFSA-Q-2018-00552	L-Cysteine monohydrochloride monohydrate by fermentation with <i>Escherichia coli</i> KCCM 80180 and <i>Escherichia coli</i> KCCM 80181 (L-cysteine monohydrochloride monohydrate (feed grade)) for all animal species
EFSA-Q-2018-00622	Ronozyme® WX (CT) / Ronozyme® WX (L) (endo-1,4-beta-xylanase) for sows for reproduction
EFSA-Q-2018-00584	<i>Bacillus subtilis</i> DSM 28343 for pigs for fattening
EFSA-Q-2018-00612	L-Arginine produced with <i>Corynebacterium glutamicum</i> KCCM 80182 (L-Arginine feed grade) for all animal species
EFSA-Q-2018-00627	L-Threonine produced with <i>Corynebacterium glutamicum</i> KCCM 80178 (THR Pro feed grade) for all animal species

EFSA-Q-2018-00630	Levucell SC (<i>Saccharomyces cerevisiae</i> CNCM I-1077) for calves and other (pseudo)ruminants species at the corresponding developmental stage
EFSA-Q-2018-00631	Levucell SB (<i>Saccharomyces cerevisiae</i> CNCM I-1079) for turkeys for fattening
EFSA-Q-2018-00623	Natuphos® E (6-phytase) for chickens for fattening, chickens reared for laying and breeding
EFSA-Q-2018-00632	Bactocell (<i>Pediococcus acidilactici</i> CNCM MA 18/5M) for all fish (including ornamental fish) and all crustaceans (including ornamental crustaceans)
EFSA-Q-2018-00641	Bactocell (<i>Pediococcus acidilactici</i> CNCM MA 18/5M) for all birds/avian species and categories and all growing pig/suidae species and categories
EFSA-Q-2018-00678	ZM16 (<i>Bacillus amyloliquefaciens</i> DSM 25840) for pigs for fattening, sows, piglets (weaned, suckling) and other minor porcine species
EFSA-Q-2018-00679	EB15 (<i>Bacillus subtilis</i> DSM 25841) for pigs for fattening, sows, piglets (weaned, suckling) and other minor porcine species
EFSA-Q-2018-00647	Bonvital (<i>Enterococcus faecium</i> DSM 7134) for sows for reproduction
EFSA-Q-2018-00693	L-Glutamine produced using strain <i>Corynebacterium glutamicum</i> NITE BP-02524 for all animal species
EFSA-Q-2018-00668	BioPlus® 2B (<i>Bacillus licheniformis</i> DSM 5749 and <i>Bacillus subtilis</i> DSM 5750) for turkeys for fattening
EFSA-Q-2018-00677	Calsporin® (<i>Bacillus subtilis</i> C-3102, DSM 15544) for all poultry species
EFSA-Q-2018-00689	Zinc chelate of ethylenediamine (ZnEDA) for all animal species
EFSA-Q-2018-00690	<i>Bacillus licheniformis</i> ENV01/DSM 32457 (Optimize) for all animal species
EFSA-Q-2018-00712	L-Valine produced by fermentation with <i>Escherichia coli</i> K12 KCCM 80159 for all animal species
EFSA-Q-2018-00713	Manganese chelate of ethylenediamine (MnEDA) 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-2018-00680	Lemon extract for all animal species	12/09/2018
EFSA-Q-2018-00616	Rosemary extract for all animal species	11/09/2018
EFSA-Q-2018-00617	Sus scrofa (extract from defatted porcine pancreatic glands) for cats and dogs and other carnivorous and omnivorous companion animals such as ferrets	11/09/2018
EFSA-Q-2018-00621	Olive extract, olive leaf extract (<i>Olea europaea</i> L.) for all animal species	11/09/2018

EFSA-Q-2018-00268	Minalac (<i>Pediococcus acidilactici</i> DSM 13943, <i>Lactobacillus plantarum</i> DSM 8862 and <i>Lactobacillus plantarum</i> DSM 8866) for minks (<i>Neovison vison</i>)	13/07/2018
EFSA-Q-2018-00438	L-Histidine monohydrochloride monohydrate (feed grade) produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80172 for all animal species	09/07/2018
EFSA-Q-2018-00427	L-Lysine formulated as L-lysine monohydrochloride and L-lysine sulphate for all animal species	03/07/2018
EFSA-Q-2018-00428	CarvaDigest (Carvacrol) for salmon and trout	03/07/2018
EFSA-Q-2018-00477	Availa-Cr (chromium chelate of DL-methionine) for dairy cows	21/08/2018
EFSA-Q-2018-00417	Natugrain® TS, Natugrain® TS L (endo-1,4-beta-xylanase and endo-1,4-beta-glucanase) for piglets (weaned), laying hens, chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, turkeys for breeding purposes, ducks for fattening, all minor avian species for laying, minor poultry species for fattening (other than ducks for fattening) and ornamental birds	30/07/2018
EFSA-Q-2018-00418	Biomin® DC-P (Preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol) for chickens for fattening, chickens reared for laying and minor avian species other than laying species	02/07/2018
EFSA-Q-2018-00419	Bonvital (<i>Enterococcus faecium</i> DSM 7134) for laying hens	02/07/2018
EFSA-Q-2018-00420	Hostazym (endo-1,4-beta-xylanase) for rabbits for fattening	06/08/2018
EFSA-Q-2018-00421	CIBENZA® PHYTAVERSE® G10, CIBENZA® PHYTAVERSE® L10 (6-phytase) for piglets (weaned), pigs for fattening, sows for reproduction, minor porcine species, chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, minor avian species excluding laying birds, minor avian species for laying	30/07/2018
EFSA-Q-2018-00422	Sorbiflore® Advance (<i>Lactobacillus rhamnosus</i> and <i>Lactobacillus farciminis</i>) for piglets (weaned)	24/08/2018
EFSA-Q-2018-00442	L-lysine monohydrochloride and concentrated liquid Lysine, produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 10227 for all animal species	10/07/2018
EFSA-Q-2018-00473	Levucell® SB (<i>Saccharomyces cerevisiae</i> CNCM I-1079) for piglets (suckling), pigs for fattening, minor pig categories and minor porcine species	16/07/2018
EFSA-Q-2018-00478	APSA PHYTAFEED® 20,000 GR, APSA PHYTAFEED® 20,000 L (6-phytase) for chickens for fattening, chickens reared for laying and minor poultry species	18/07/2018
EFSA-Q-2018-00474	Biosprint® (<i>Saccharomyces cerevisiae</i> MUCL 39885) for sows	22/08/2018
EFSA-Q-2018-00451	L-Tryptophan produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80176 (L-Tryptophan feed grade) for all animal species	10/07/2018

EFSA-Q-2018-00516	PHYZYME® XP 10000 TPT, PHYZYME® XP 10000 L (6-phytase) for all avian species and all swine species	07/08/2018
EFSA-Q-2018-00506	L-Threonine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80117 (L-Threonine feed grade) for all animal species	31/07/2018
EFSA-Q-2018-00545	L-Tryptophan produced by fermentation with <i>Escherichia coli</i> KCCM 10534 (L-Tryptophan feed grade) for all animal species	18/09/2018
EFSA-Q-2018-00546	L-Histidine monohydrochloride monohydrate for other fin fish	20/08/2018
EFSA-Q-2018-00547	L-Histidine monohydrochloride monohydrate produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80179 for all animal species	18/09/2018
EFSA-Q-2018-00548	L-Leucine produced using strain NITE BP-02351 for all animal species	20/08/2018
EFSA-Q-2018-00622	Ronozyme® WX (CT) / Ronozyme® WX (L) (endo-1,4-beta-xylanase) for sows for reproduction	19/09/2018
EFSA-Q-2018-00584	<i>Bacillus subtilis</i> DSM 28343 for pigs for fattening	29/08/2018
EFSA-Q-2018-00630	Levucell SC (<i>Saccharomyces cerevisiae</i> CNCM I-1077) for calves and other (pseudo)ruminants species at the corresponding developmental stage	25/09/2018
EFSA-Q-2018-00631	Levucell SB (<i>Saccharomyces cerevisiae</i> CNCM I-1079) for turkeys for fattening	25/09/2018
EFSA-Q-2018-00623	Natuphos® E (6-phytase) for chickens for fattening, chickens reared for laying and breeding	19/09/2018
EFSA-Q-2018-00632	Bactocell (<i>Pediococcus acidilactici</i> CNCM MA 18/5M) for all fish (including ornamental fish) and all crustaceans (including ornamental crustaceans)	25/09/2018

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-2018-00511	Vitamin D3 as feed additive for salmonids
EFSA-Q-2018-00695	L-Threonine produced by <i>Escherichia coli</i> CGMCC 11473 for all animal species
EFSA-Q-2018-00669	Beltherm MP and Beltherm ML (endo-1,4-beta-xylanase) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, turkeys for breeding purposes, and minor poultry species

These questions were assigned to the respective working groups.

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

7.1. EFSA

a) New way of work

The FEED unit is piloting a project to improve the efficiency of the assessment of applications. The Panel was informed on the main aspects of this project, which involve a higher degree of in house work in the preparation of scientific opinions for the authorisation of feed additives, the reduction of the number of dossiers' discussions in the WG as well as of the number of WGs, which will be mainly organised based on areas of expertise rather than on groups of additives (see point 9 below). The experts of the Panel were also invited to find ways to streamline the process of assessment and adoption of opinions.

7.2. European Commission

Christoph von Holst presented the role and the work of the European Union Reference Laboratory with regards to the authorisation of feed additives.

8. Other scientific topics for information and/or discussion

Not discussed

9. Agreement on Working Groups and appointment of Working Group Chairs

The Panel confirmed the need for the following existing Working Groups:

- Technological additives, with the same remit
- Feed flavourings, with the same remit
- Amino acids and vitamins, with an update of the remit to cover the ongoing applications on trace elements. The WG will be renamed as Nutritional additives
- Other additives with an update of the remit to cover the ongoing applications not covered in the WGs above

These WGs will be responsible to finalise the assessment of the ongoing applications, and it is foreseen that they will be closed once the assessment of these applications is completed.

At the same time the Panel agreed on the need for the following WGs, which will be responsible for the assessment of the relevant new applications (those submitted as of October 2018):

- Animal nutrition

- Microbiology
- Toxicology
- Environment

The Chair of the Panel in collaboration with the Head of the FEED Unit identified and nominated the Chairs of these Working Groups as follows:

Working Group	Chair
Technological additives	Gabriele Aquilina
Feed flavourings	Birgit Dusemund
Nutritional additives	Fernando Ramos
Other additives	Maryline Kouba
Animal nutrition	Vasileios Bampidis
Microbiology	Baltasar Mayo
Toxicology	Roberto Villa
Environment	Giovanna Azimonti

The experts of the Panel were assigned to the new WGs based on their area of expertise.

10. Any other business

Not discussed