

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

Minutes of the 129th Plenary meeting

Held on 28-30 November 2017, Parma (Italy)

(Agreed by written procedure on 7 December 2017)

Participants

■ Panel Members

Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis¹, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Coconcelli, Gerhard Flachowsky, Jürgen Gropp², Boris Kolar, Maryline Kouba, Marta López-Alonso, Secundino López Puente³, Alberto Mantovani, Baltasar Mayo⁴, Guido Rychen, Maria Saarela, Roberto Edoardo Villa⁵, Robert John Wallace and Pieter Wester.

■ Hearing Experts:

N/A

■ European Commission and/or Member States representatives:

Marta Ponghellini (DG SANTE).

■ EFSA:

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

LA Unit: Simone Gabbi⁶

AFSCO Unit: Stef Bronzwaer⁷

¹ Participated via webconference.

² Participated only on 28 November.

³ Participated via webconference.

⁴ Participated only on 28 and 29 November.

⁵ Participated only on 28 and 29 November.

⁶ Participated only on 28 November for item 7.1.b.

⁷ Participated only on 29 November for item 7.1.c.

1. Welcome and apologies for absence

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

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 Processes⁸ and the Decision of the Executive Director on Declarations of Interest⁹, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Panel Members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 128th Plenary meeting held on 26-28 September 2017

The minutes of the 128th Plenary meeting held on 26-28 September 2017 were agreed by written procedure on 9 October 2017.¹⁰

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

5.1 Sodium saccharin for piglets (suckling and weaned), pigs for fattening, calves for rearing and calves for fattening ([EFSA-Q-2010-01228](#))

Not discussed due to lack of time.

5.2 Monimax® (monensin sodium and nicarbazin) for chickens for fattening, chickens reared for laying and turkeys for fattening ([EFSA-Q-2012-00791](#) and [EFSA-Q-2012-00906](#))

A member of the working group (WG) presented the questions and the draft opinion. These questions refer to the authorisation under

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁹ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

¹⁰ <http://www.efsa.europa.eu/sites/default/files/event/170926-m.pdf>

Article 4 of Regulation (EC) No 1831/2003 of Monimax as a coccidiostat for chickens for fattening, chickens reared for laying and turkeys for fattening.

The draft opinion was discussed. Discussion focussed mainly on the safety for the target species, consumer, user and environment and on the efficacy. The Panel unanimously adopted the part of the opinion covering turkeys. The Panel agreed that further data are needed to complete the assessment regarding chickens for fattening and chickens reared for laying.

5.3 ENZY CARBOPLUS® preparation of xylanase (EC 3.2.1.8) and beta-glucanase (EC 3.2.1.6) for chickens for fattening, laying hens, turkeys for fattening, piglets (weaned), minor porcine species, avian species (game birds, ducks, geese, pigeons, sporting and ornamental birds) including laying birds, chickens reared for laying and turkeys reared for breeding ([EFSA-Q-2013-00528](#))

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the enzyme preparation ENZY CARBOPLUS® as a zootechnical additive for avian and porcine species.

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

5.4 Coxiril® (diclazuril) for chickens reared for laying ([EFSA-Q-2015-00616](#))

Not discussed due to lack of time.

5.5 Vevovitall (benzoic acid) for weaned piglets and pigs for fattening ([EFSA-Q-2016-00017](#))

The rapporteur presented the question and the draft opinion. This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Vevovitall as a zootechnical additive for weaned piglets and pigs for fattening.

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

5.6 Natural essential oil from *Origanum vulgare* L. ssp. *hirtum* var. *Vulkan* (DOS 00001) for all animal species ([EFSA-Q-2016-00112](#))

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC)

No 1831/2003 of natural essential oil from *Origanum vulgare* L. ssp. hirtum var. Vulkan as a sensory additive for all animal species.

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

5.7 Preparation of HMTBa and calcium salt of HMTBa for all animal species ([EFSA-Q-2016-00370](#))

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the hydroxy analogue of methionine and calcium salt of hydroxy analogue of methionine as a nutritional additive for all animal species.

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

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

The Chair of the WG presented the question and the draft guidance. 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 Chair of the WG gave an overview of the main changes with respect to the current guidance. A detailed discussion will take place in a next plenary.

5.9 Zinc-L-selenomethionine for all animal species ([EFSA-Q-2016-00554](#))

Not discussed due to lack of time.

5.10 Bentonite for all animal species ([EFSA-Q-2016-00561](#))

The Chair of the WG presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of bentonites as technological additives for all animal species.

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

5.11 Benzoic acid for suckling piglets, weaned piglets, pigs for fattening, sows for reproduction, sows in order to have benefit in piglets, minor porcine species, chickens

for fattening, chickens reared for laying, laying hens, breeding hens, turkeys for fattening, turkeys for breeding purposes, turkeys reared for breeding, minor poultry species ([EFSA-Q-2016-00858](#))

Not discussed due to lack of time.

5.12 Guidance on the assessment of the efficacy of feed additives ([EFSA-Q-2017-00246](#))

A member of the WG presented the question and the draft guidance. This question refers to the self-task of the Panel on the revision of the guidance documents.

The draft guidance was discussed. This document covers the assessment of the efficacy of feed additives. The draft guidance was endorsed for public consultation.

5.13 Coxiril® (diclazuril) for pheasants ([EFSA-Q-2017-00482](#))

Not discussed due to lack of time.

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-2017-00724	Preparation of bacteriophages (3sent1, 8sent65, 8sent1748 and 5sent1) for all avian species
EFSA-Q-2017-00694	Red carotenoid rich <i>Paracoccus carotinifaciens</i> for salmon and trout
EFSA-Q-2017-00693	L-Tryptophan produced by fermentation with <i>Escherichia coli</i> K12 KCCM80152 for all animal species
EFSA-Q-2017-00717	endo-1,4-beta-glucanase, alpha-amylase and protease for chickens for fattening, laying hens and all minor poultry species
EFSA-Q-2017-00716	<i>Bacillus subtilis</i> DSM 29784 for minor poultry species for fattening and reared for laying
EFSA-Q-2017-00722	<i>Bacillus amyloliquefaciens</i> DSM 25840 for all animal species
EFSA-Q-2017-00743	Tocopheryl phosphate mixture for all animal species
EFSA-Q-2017-00744	<i>Bacillus subtilis</i> DSM 32324 for all animal species

EFSA-Q-2017-00745	<i>Bacillus subtilis</i> DSM 32325 for all animal species
EFSA-Q-2017-00746	<i>Bacillus amyloliquefaciens</i> AGTP BS918 (NRRL B-50508), <i>Bacillus amyloliquefaciens</i> AGTP BS1013 (NRRL B-50509), <i>Bacillus subtilis</i> AGTP BS3BP5 (NRRL B-50510) for pigs for fattening and minor porcine species
EFSA-Q-2017-00747	Endo-1,4-beta-xylanase for sows

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-2016-00711	<i>Lactobacillus farciminis</i> CNCM MA67/4R for laying hens, chickens and turkeys for fattening	18/10/2017
EFSA-Q-2017-00661	Salinomycin sodium for rabbits for fattening	04/10/2017
EFSA-Q-2017-00023	<i>Lactobacillus plantarum</i> JI:1 (DSM 115 20) for horses	23/10/2017
EFSA-Q-2017-00387	Preparation of 3-phytase (EC 3.1.3.8) produced by <i>Komagataella pastoris</i> (CECT 13094) for chickens reared for laying and minor poultry species	27/10/2017
EFSA-Q-2017-00446	6-phytase for pigs for fattening	29/09/2017
EFSA-Q-2017-00503	Aluminosilicate of sodium, potassium, calcium and magnesium for pigs	08/11/2017
EFSA-Q-2017-00447	Preparation of 3-phytase (EC 3.1.3.8) produced by <i>Komagataella pastoris</i> (CECT 13094) for pigs for fattening and minor porcine species for growing	07/11/2017
EFSA-Q-2017-00499	Astaxanthin dimethyldisuccinate for salmon and trout, crustaceans and other fish	19/10/2017
EFSA-Q-2017-00483	L-Valine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM11201P for all animal species	09/11/2017
EFSA-Q-2017-00609	L-threonine for all animal species	04/10/2017
EFSA-Q-2017-00610	L-tryptophan for all animal species	04/10/2017
EFSA-Q-2017-00650	Preparation of 3-phytase (EC 3.1.3.8) produced by <i>Komagataella pastoris</i> (CECT 13094) for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying, laying hens and minor poultry species for laying, pigs for fattening and minor porcine species for growing	19/10/2017
EFSA-Q-2017-00632	Muramidase produced by <i>Trichoderma reesei</i> DSM 32338 for chickens for fattening and minor poultry species	12/10/2017
EFSA-Q-2017-00662	Extract from super critical carbon dioxide extraction of <i>Humulus lupulus</i> L. flos containing 40% beta acids with propylene glycol (Beta Rich	25/10/2017

	Hop Extract - BRHE) for all animal species	
EFSA-Q-2017-00694	Red carotenoid rich <i>Paracoccus carotinifaciens</i> for salmon and trout	20/11/2017
EFSA-Q-2017-00648	Benzoic acid for pigs for fattening	17/10/2017
EFSA-Q-2017-00651	Endo-1,4-beta-xylanase, endo-1,4-beta-glucanase for sows in order to have benefit in piglets	20/10/2017

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-2017-00682	Endo-1,4-beta-xylanase for (weaned) piglets and chickens for fattening

This question was assigned to the respective working group.

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

7.1 EFSA

- a) Manuela Tiramani informed the Panel that as of 1st December she will take the post of Head of Unit, which she has filled in since January 2015 as *ad interim*.
- b) A member of the LA Unit presented the new rules on competing interest management implementing the [Policy on Independence](#) adopted at the Management Board meeting in June this year. The rules will come into force on 1 December 2017 for the DoI screening embedded in the 2018 panel renewal process, and on 1 July 2018 for all other processes.
- c) The Head of the AFSCO Unit informed the Panel on the Risk Assessment Research Assembly (RARA), as well as the call on the European FOod Risk Assessment Fellowship Programme (EU-FORA).
- d) The next open plenary of the FEEDAP Panel will take place on 17-19 April 2018. The Panel was also informed on the feedback received from observers of the last open plenary meeting. In general observers appreciated the opportunity to follow the plenary meeting.

7.2 Scientific Committee

- a) The Chair of the Panel reported on the last meeting of the Scientific Committee, and highlighted that the EFSA Guidance on Uncertainty Analysis in Scientific Assessment was adopted.

7.3 Working Groups

Not discussed.

8. Other scientific topics for information and/or discussion

Not discussed.

9. Any other business

- a)** The Panel agreed to hold a plenary meeting on 6-7 March 2018, in addition to those already planned for 2018.