

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

Minutes of the 130th Plenary meeting

Held on 20-22 February 2018, Parma (Italy)

(Agreed by written procedure on 1 March 2018)

Participants

■ Panel Members

Gabriele Aquilina, Giovanna Azimonti¹, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Coconcelli², Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Marta López-Alonso, Secundino López Puente³, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, 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, Niovi Kordali, Gloria López-Gálvez, Paola Manini, Jordi Tarrés-Call, Manuela Tiramani and Maria Vittoria Vettori.

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received. The Chair welcomed also Niovi Kordali, the new trainee in the Feed Unit.

¹ Participated only on 20 and 21 February.

² Not present on 21 February AM.

³ Participated via webconference.

2. Adoption of agenda

The agenda was adopted after the deletion of the item "Alpha-amylase from *Bacillus amyloliquefaciens* DSM 9553, *Bacillus amyloliquefaciens* NCIMB 30251, *Aspergillus oryzae* CBS 585.94 and *Aspergillus oryzae* ATTC SD-5374, endo-1,4-beta-glucanase from *Trichoderma reesei* ATCC PTA-10001, *Trichoderma reesei* ATCC SD-6331 and *Aspergillus niger* CBS 120604, endo-1,4-beta-xylanase from *Trichoderma koningii* MUCL 39203 and *Trichoderma longibrachiatum* CBS 614.94 and endo-1,3(4)-beta-glucanase from *Aspergillus tubingensis* MUCL 39199 for all animal species ([EFSA-Q-2012-00411](#))".

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 and the Specific Declarations of Interest filled in by the Panel Members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 129th Plenary meeting held on 28-30 November 2017

The minutes of the 129th Plenary meeting held on 28-30 November 2017 were agreed by written procedure on 7 December 2017.⁶

5. Report on the written procedures since 129th Plenary meeting

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

This opinion was adopted during the last plenary meeting on 30 November 2017. The Panel withdraw the adoption of the opinion on 18 January 2018 by written procedure since some issues were identified in the efficacy section which require discussion in the Panel.

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/171128-m.pdf>

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

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

The Chair of the working group (WG) presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of sodium saccharin as a sensory additive for piglets, pigs for fattening, calves for rearing and calves 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 opinion.

6.2. Butylated hydroxy anisole (BHA) for all animal species ([EFSA-Q-2011-00942](#))

Not discussed due to lack of time

6.3. Ponceau 4R for dogs, cats and ornamental fish ([EFSA-Q-2012-00331](#))

Not discussed due to lack of time

6.4. Natural mixtures of talc (steatite) and chlorite (E 560) for all animal species ([EFSA-Q-2014-00634](#))

The Chair of the WG presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of natural mixtures of talc (steatite) and chlorite as a technological additive for all animal species.

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

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

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 Coxiril as a coccidiostat for chickens reared for laying.

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

6.6. 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 opinion was originally adopted in November 2017, but some issues were identified in the efficacy section for non-ruminants. The Panel decided to withdraw the adoption of the opinion (see 5.1). The WG was asked to revise the opinion to consider additional publications.

The revised draft opinion was discussed. Discussion focussed on the efficacy of the additive for non-ruminants. The opinion was unanimously adopted.

6.7. 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 draft guidance was discussed in detail. The Panel agreed that further discussion is needed and decided to continue the discussion in a future plenary.

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

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 zinc-L-selenomethionine as a nutritional additive for all animal species.

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

6.9. EB15 (*Bacillus subtilis* DSM 25841) for weaned piglets and weaned minor porcine species ([EFSA-Q-2016-00781](#))

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 EB15 (*Bacillus subtilis* DSM 25841) as a

zootechnical additive for weaned piglets and weaned minor porcine species.

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

6.10. ZM16 (*Bacillus amyloliquefaciens* DSM 25840) for weaned piglets and weaned minor porcine species ([EFSA-Q-2016-00782](#))

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 ZM16 (*Bacillus amyloliquefaciens* DSM 25840) as a zootechnical additive for weaned piglets and weaned minor porcine species.

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

6.11. 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](#))

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 benzoic acid as a zootechnical additive for porcine and avian species.

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

6.12. *Bacillus subtilis* DSM 28343 for calves for rearing ([EFSA-Q-2017-00090](#))

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 *Bacillus subtilis* DSM 28343 as a zootechnical additive for calves for rearing.

The draft opinion was discussed, focusing mainly on the efficacy of the additive. The draft opinion will be amended according to the discussions and will be presented for adoption in the next plenary meeting.

6.13. Guidance on the characterisation of microorganisms used as feed additives or as production organisms ([EFSA-Q-2016-00069](#) and [EFSA-Q-2017-00211](#))

The rapporteur 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 requirements for the proper characterisation of microbial strains used as feed additives or as a source of them, and also some particular requirements for feed additives produced by microbial fermentation, including those related to the genetic modification of microorganisms used as production strains.

The draft guidance was endorsed by the FEEDAP Panel for public consultation on 18 May 2017. Discussion focussed on the modifications introduced in the guidance following the comments received in the public consultation. The guidance was unanimously adopted.

The Panel also endorsed the technical report prepared by the FEED Unit regarding the outcome of the public consultation.

6.14. Preparation of 3-phytase produced by fermentation of a genetically modified strain of *Komagataella pastoris* (CECT 13094) for chickens reared for laying and minor poultry species ([EFSA-Q-2017-00387](#))

A member of the FEED Unit presented the question and the draft opinion. 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 chickens reared for laying and minor poultry species.

The draft opinion was discussed. Discussion focussed mainly on the safety for the target species and the efficacy. The Panel unanimously adopted the opinion.

6.15. *Pediococcus pentosaceus* DSM 32291 for all animal species ([EFSA-Q-2017-00449](#))

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 *Pediococcus pentosaceus* DSM 32291 as a technological additive for all animal species.

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

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

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 Coxiril as a coccidiostat for pheasants.

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

6.17. Cylactin (*Enterococcus faecium* NCIMB 10415) for pigs for fattening ([EFSA-Q-2017-00525](#))

The rapporteur presented the question and the draft opinion. EFSA was requested by the European Commission to deliver an opinion on the efficacy of Cylactin (*Enterococcus faecium* NCIMB 10415) as a zootechnical additive for pigs for fattening based on the additional data provided by the applicant.

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

6.18. Sacox® (salinomycin sodium) for rabbits for fattening ([EFSA-Q-2017-00661](#))

The rapporteur presented the question and the draft opinion. This question refers to the urgent authorisation under Article 15 of Regulation (EC) No 1831/2003 of Sacox® as a coccidiostat for rabbits for fattening.

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

6.19. Alterion® NE (*Bacillus subtilis* DSM 29784) for minor poultry species ([EFSA-Q-2017-00716](#))

A member of the FEED Unit presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Alterion® NE (*Bacillus subtilis* DSM 29784) as a zootechnical additive for minor poultry species for fattening and reared for laying.

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

7. New mandates

7.1. 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-2017-00749	Endo-1,4-beta-xylanase for piglets (weaned), pigs for fattening and other porcine species
EFSA-Q-2017-00754	<i>Lactobacillus rhamnosus</i> CNCM I-3698 and <i>Lactobacillus farciminis</i> CNCM I-3699 for all animal species
EFSA-Q-2017-00755	<i>Lactobacillus rhamnosus</i> and <i>Lactobacillus farciminis</i> for suckling and weaned piglets
EFSA-Q-2017-00756	<i>Lactobacillus rhamnosus</i> and <i>Lactobacillus farciminis</i> for chickens for fattening
EFSA-Q-2017-00837	Endo-1,4-beta-xylanase and alpha-galactosidase for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying
EFSA-Q-2018-00060	<i>Bacillus amyloliquefaciens</i> CECT 5940 for chickens for fattening and reared for laying
EFSA-Q-2018-00083	<i>Saccharomyces cerevisiae</i> CNCM I-1077 for Lambs and horses
EFSA-Q-2018-00011	Copper chelates of lysine and glutamic acid for all animal species
EFSA-Q-2018-00012	Zinc chelates of lysine and glutamic acid for all animal species
EFSA-Q-2018-00084	L-Threonine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM80118 for all animal species

7.2. 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-2010-01066	<i>Macleaya cordata</i> extract for all animal species	08/02/2018
EFSA-Q-2010-01311	<i>Melissa officinalis</i> dry extract for all animal species	19/01/2018
EFSA-Q-2010-01289	<i>Origanum heracleoticum</i> L. for Suckling piglets, weaned piglets, pigs for fattening, sows for reproduction, sows for benefits in piglets, chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening and breading and reared for breeding, calves for rearing, veal production, cattle for fattening, dairy cows for	19/01/2018

	milk production, cows for reproduction, lambs for rearing, lambs for fattening, dairy sheep for milk production, ewes for reproduction, kids for rearing, kids for fattening, dairy goats for milk production, goats for reproduction, fin fish, shrimps	
EFSA-Q-2011-00146	Denseflower mullein tincture for all animal species	08/02/2018
EFSA-Q-2011-00181	Mugwort tincture for all animal species	08/02/2018
EFSA-Q-2017-00724	Preparation of bacteriophages (3sent1, 8sent65, 8sent1748 & 5sent1) for all avian species	22/01/2018
EFSA-Q-2017-00627	Mixture of ZnEDTA and Cu(NH4)2EDTA chelates, on chicory pulp carrier, supplemented with 3b E6 ZnO and 3b E4 CuO for pigs	27/11/2017
EFSA-Q-2017-00644	Sodium selenite for ruminants	06/12/2017
EFSA-Q-2017-00717	Endo-1,4-beta-xylanase, alpha-amylase and protease for chickens for fattening, laying hens and all minor poultry species	13/12/2017
EFSA-Q-2017-00716	<i>Bacillus subtilis</i> DSM 29784 for minor poultry species for fattening and reared for laying	13/12/2017
EFSA-Q-2017-00722	<i>Bacillus amyloliquefaciens</i> DSM 25840 for all animal species	15/12/2017
EFSA-Q-2017-00744	<i>Bacillus subtilis</i> DSM 32324 for all animal species	08/01/2018
EFSA-Q-2017-00745	<i>Bacillus subtilis</i> DSM 32325 for all animal species	08/01/2018
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	08/01/2018
EFSA-Q-2017-00749	Endo-1,4-beta-xylanase for piglets (weaned), pigs for fattening and other porcine species	12/01/2018
EFSA-Q-2017-00747	Endo-1,4-beta-xylanase for sows	12/02/2018

These applications were assigned to the respective working groups.

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

EFSA-Q-Number	Subject
EFSA-Q-2018-00001	Endo-1,3(4)-beta-glucanase, endo-1,4-beta-xylanase and alpha-amylase
EFSA-Q-2018-00050	Endo-1,4-beta-mannanase, EC 3.2.1.78
EFSA-Q-2018-00013	Ethoxyquin (6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline)
EFSA-Q-2018-00010	Natural mixture of dolomite plus magnesite and magnesium-phyllosilicates

These questions were assigned to the respective working group.

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

8.1. EFSA

- a) The Panel was informed of the EFSA's 24th Scientific Colloquium on "OMICS in risk assessment: state-of-the-art and next steps" which will take place on 24-25 April 2018 in Berlin, Germany. It will explore the opportunities for integration of datasets produced via specific OMICS tools within the remit of EFSA's risk assessment approaches.
- b) The Head of Unit informed the Panel that due to organisational issues the Infosession which was originally scheduled for June 2018 has been cancelled. Alternative initiatives of engagement with the stakeholders are being considered.
- c) The Panel was also informed regarding the status of the renewal of the EFSA's Scientific Panels and Scientific Committee. The Management Board decision on the final composition of the Scientific Panels/Scientific Committee will take place by the end of March 2018.

8.2. Scientific Committee

Not discussed.

8.3. Working Groups

Not discussed.

9. Other scientific topics for information and/or discussion

- a) The Panel was informed about an erratum identified in the opinion on "Safety and efficacy of iron compounds (E1) as feed additives for all animal species, based on a dossier submitted by FEFANA asbl" (EFSA-Q-2012-00491) adopted on 27 January 2016. This erratum will be corrected.

10. Any other business

- a) The Chair of the Panel informed that Prof. Secundino López resigned as Vice-Chair of the Panel and as Chair of the WG on Other additives. At the same time, the Panel was informed that Alberto Mantovani has been appointed as Chair of the WG on Other additives.
- b) The Panel elected Roberto Villa as Vice-Chair of the Panel.

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In the ADoI or in the SDoI filled for the present meeting Dr. Baltasar Mayo declared the following interest: his laboratory performed some analysis for the applicant of the product *Pediococcus pentosaceus* DSM 32291. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in exclusion of the expert from any discussion, voting or other processing of item 6.16 *Pediococcus pentosaceus* DSM 32291 for all animal species ([EFSA-Q-2017-00449](#)) by the concerned scientific group.

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>