

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

Minutes of the 124th Plenary meeting

Held on 24-26 January 2017, Parma (Italy)

(Agreed by written procedure on 2 February 2017)

Participants

■ Panel Members

Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli,¹ Gerhard Flachowsky, Jürgen Gropp,² Boris Kolar, Maryline Kouba, Marta López Alonso, Secundino López Puente, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

■ Hearing Experts:

Andy Hart³

■ European Commission and/or Member States representatives:

Luis Vivas-Alegre (DG SANTE)

■ EFSA:

FEED Unit: Jaime Aguilera, Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini, Jordi Tarrés-Call and Manuela Tiramani.

AMU Unit: Elisa Aiassa⁴

SCER Unit: Andrea Germini⁵

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

¹ Present on 24 and 26 January

² Present on 24 January for item 5.3 via tele-webconference

³ Present on 25 January for item 7.3.d. via tele-webconference

⁴ Present only 25 January for point 7.3.d

⁵ Present only 25 January for point 7.3.d

2. Adoption of agenda

The agenda was adopted with the deletion of the items “Avatec[®] 150G (Lasalocid A sodium) for chickens for fattening, chickens reared for laying, turkeys for fattening, minor avian species (pheasants, guinea fowl, quails and partridges), except laying birds (EFSA-Q-2013-00813)”, “Organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 (Selenised yeast inactivated) (SEL-PLEX) for all animal species (EFSA-Q-2016-00138)”, *Bacillus subtilis* PB6 (*Bacillus subtilis* ATCC PTA-6737) for sows, in order to have benefits in piglets (EFSA-Q-2014-00587)” and “Levucell[®] SB (*Saccharomyces cerevisiae* CNCM I-1079) for weaned piglets and sows (EFSA-Q-2016-00449)”.

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, 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 the Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interests were declared.

4. Agreement of the minutes of the 123rd Plenary meeting held on 6-8 December 2016

The minutes of the 123rd Plenary meeting held on 6-8 December 2016 were agreed by written procedure on 15 December 2016.⁸

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

5.1 Endofeed[®] DC (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase) chickens for fattening, laying hens, pigs for fattening, minor poultry species and minor porcine species ([EFSA-Q-2014-00504](http://www.efsa.europa.eu/en/keydocs/docs/independencerule2014.pdf))

The Chair of the working group (WG) presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety of Endofeed[®] DC (endo-1,3(4)-beta-glucanase and endo-1,4-

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencerule2014.pdf>

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencerule2014.pdf>

⁸ <http://www.efsa.europa.eu/sites/default/files/event/161018a-m.pdf>

beta-xylanase) as a zootechnical additive for poultry and pigs based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive and the safety for the consumer. The opinion was adopted.

5.2 Bergazym[®] P 100 (Endo-1,4- β -xylanase) for chickens for fattening, piglets (weaned), pigs for fattening ([EFSA-Q-2014-00586](#))

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 Bergazym[®] P100 (endo-1,4- β -xylanase) as a zootechnical additive for chickens for fattening, piglets (weaned) and pigs for fattening.

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

5.3 Iron dextran for piglets ([EFSA-Q-2014-00592](#))

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 Iron dextran as a nutritional additive for piglets.

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

5.4 Vitamin D₃ addition to feedingstuffs for fish ([EFSA-Q-2014-00604](#))

The rapporteur presented the question and the draft opinion. EFSA has been requested to assess the safety of increasing the current authorised levels of vitamin D₃ in feedingstuffs for fish.

The draft opinion was discussed. Discussion focused mainly on the safety for the target species and for the consumer in relation with the proposed increase in the maximum authorised level for fish. The opinion was adopted.

5.5 Hostazym[®] X (endo-1,4-beta-xylanase) for chickens reared for laying and minor poultry species reared for laying ([EFSA-Q-2015-00834](#))

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 Hostazym[®] X (endo-1,4- β -xylanase) as a

zootechnical additive for chickens reared for laying and minor poultry species reared for laying.

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

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

Not discussed due to lack of time.

5.7 *Saccharomyces cerevisiae* NBRC 0203, *Lactobacillus plantarum* NBRC 3070 and *Lactobacillus casei* NBRC 3425 for all animals species ([EFSA-Q-2016-00130](#))

The rapporteur presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the efficacy of *Saccharomyces cerevisiae* NBRC 0203, *Lactobacillus plantarum* NBRC 3070 and *Lactobacillus casei* NBRC 3425 as a technological additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focussed mainly on the efficacy. The opinion was adopted.

5.8 *Pediococcus parvulus* DSM 28875 for all species ([EFSA-Q-2016-00236](#))

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 parvulus* DSM 28875 as a technological additive for all animal species.

The draft opinion was discussed. Discussion focused on the characterisation and on the efficacy. The opinion was adopted.

5.9 *Lactobacillus casei* DSM 28872 for all species ([EFSA-Q-2016-00237](#))

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 *Lactobacillus casei* DSM 28872 as a technological additive for all animal species.

The draft opinion was discussed. Discussion focused on the characterisation and on the efficacy. The opinion was adopted.

5.10 Natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol) for all animal species ([EFSA-Q-2016-00459](#))

A member of the WG presented the question and the draft opinion. EFSA has been requested to assess the safety of a natural mixture of dolomite plus magnesite and magnesium-phyllsilicate when used as a technological additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focused on the safety for the target species. The opinion was adopted.

5.11 Cassia gum for dogs and cats ([EFSA-Q-2016-00461](#))

A member of the WG presented the question and the draft opinion. EFSA has been requested to assess the safety of a cassia gum when used as a technological additive for dogs and cats based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focused on the safety for the target species. The opinion was adopted.

5.12 L-tryptophan, technically pure for all animal species ([EFSA-Q-2016-00551](#))

The Vice-chair of the WG presented the question and the draft opinion. EFSA has been requested to assess the safety of L-tryptophan produced by *Escherichia coli* CGMCC 3667 when used as a nutritional additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focused on the characterisation of the genetic modification. The opinion was adopted.

5.13 L-tryptophan, technically pure, produced by *Escherichia coli* strains DSM 25084 and KCCM 11132P for all animal species ([EFSA-Q-2016-00570](#))

The rapporteur WG presented the question and the draft opinion. EFSA has been requested to assess the safety of L-tryptophan produced by *Escherichia coli* DSM 25084 and KCCM 11132P when used as a nutritional additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focused on the characterisation of the strains and safety for the user. The opinion was adopted.

5.14 *Lactobacillus hilgardii* CNCM I-4785 for all animal species ([EFSA-Q-2016-00580](#))

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 *Lactobacillus hilgardii* CNCM I-4785 as a technological additive for all animal species.

The draft opinion was discussed. The opinion will be tabled for adoption in the next plenary once the report from the European Union Reference Laboratory has been received.

5.15 Cassia gum for dogs and cats ([EFSA-Q-2016-00644](#))

A member of the WG presented the question and the draft opinion. EFSA has been requested to assess the safety of a cassia gum when used as a technological additive for dogs and cats based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focused on the safety for the target species. The opinion was adopted.

5.16 L-lysine sulphate produced by fermentation with *Escherichia coli* CGMCC 3705 for all animal species ([EFSA-Q-2016-00824](#))

The Chair of the WG presented the question and the draft opinion. EFSA has been requested to assess the safety of L-lysine sulphate produced with *Escherichia coli* CGMCC 3705 when used as a nutritional additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. Discussion focused on the characterisation of the product and the safety for the target species. The opinion was adopted.

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-2016-00783	L-Arginine for all animal species
EFSA-Q-2016-00818	Taminizer D (dimethylglycine sodium salt) for chickens for fattening
EFSA-Q-2016-00842	RONOZYME® WX (CT)/RONOZYME® WX (L)(endo-1,4-beta-xylanase) for laying hens
EFSA-Q-2017-00023	<i>Lactobacillus plantarum</i> JI:1 DSM (115 20) (ProEquo®) for horses

EFSA-Q-2017-00025	Natugrain® Wheat TS (endo-1,4-beta-xylanase) for turkeys for fattening, chickens for fattening and ducks, turkeys reared for breeding, ornamental birds, minor avian species except ducks and laying birds
EFSA-Q-2016-00858	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-2016-00861	VevoVital® (benzoic acid) for minor porcine species
EFSA-Q-2016-00868	BioWorma® (<i>Duddingtonia flagrans</i> IAH 1297) for all grazing animals

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-2016-00643	Coxidin (monensin sodium) for chickens for fattening and turkeys	09/12/2016
EFSA-Q-2016-00648	ECONASE® XT (endo-1,4-beta-xylanase) for pigs for fattening	28/11/2016
EFSA-Q-2016-00668	GalliPro® (<i>Bacillus subtilis</i> DSM 17299) for chickens for fattening	07/12/2016
EFSA-Q-2016-00568	<i>Lactococcus lactis</i> NCIMB 30160 for All animal species	29/11/2016
EFSA-Q-2016-00713	<i>Lactobacillus animalis</i> LA51 (ATCC PTA-6750) (LA51) for all animal species	23/12/2016
EFSA-Q-2016-00782	ZM16 (<i>Bacillus amyloliquefaciens</i> DSM 25840) for weaned piglets and weaned minor porcine species	13/01/2017
EFSA-Q-2015-00754	Astaxanthin-rich <i>Phaffia rhodozyma</i> (ATCC SD 5340) (AQUASTA) for Salmon and trout	03/01/2017
EFSA-Q-2016-00574	L-lysine monohydrochloride and L-lysine sulphate from <i>Corynebacterium glutamicum</i> CCTCC M 2015595 for all animal species	30/11/2016
EFSA-Q-2016-00580	<i>Lactobacillus hilgardii</i> CNCM I-4785 for all animal species	02/12/2016
EFSA-Q-2016-00781	EB15 (<i>Bacillus subtilis</i> DSM 25841) for weaned piglets and weaned minor porcine species	13/01/2017

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-2016-00824	L-lysine sulphate produced by fermentation with <i>Escherichia coli</i> CGMCC 3705 for all animal species
EFSA-Q-2016-00855	Natural mixture of illite, montmorillonite and kaolinite (Argile verte du Velay (Velay Green Clay)) for all animal 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

Not discussed.

7.2 Scientific Committee

Not discussed.

7.3 Working Groups

- a) The Chair of the WG on Genetically Modified Microorganisms informed the Panel regarding the progress of the work in the Guidance document for the risk assessment of additives produced with genetically modified microorganisms.
- b) The Chair of the WG on Guidance Update on Safety of Feed Additives for the Environment gave an overview of the progress in the work to update the guidance for the environmental risk assessment and the work plan for the next months.
- c) The Chair of the WG on Guidance update reported on the progress made in the update of the guidance on safety for target species and on the guidance on safety for the consumer.
- d) The Chair of the WG on amino acids and vitamins presented the state of the art of the FEEDAP pilot case for the application of the draft guidance on uncertainty and the principles of the PROMETHEUS project. The pilot case is expected to be finalised in March.

8. Other scientific topics for information and/or discussion

Not discussed.

9. Any other business

- a) The Panel started assessing the first applications for the renewal of authorisation under Article 14 of Regulation (EC) No 1831/2003. A discussion took place on how to frame the assessments. EFSA presented the current state of the art with regard to the renewal of authorisations under Article 14 of Regulation (EC) No 1831/2003. Further updates will be given in the next plenary meetings.

In this regard, the Panel expressed their intention that for the applications for renewal involving microorganisms, the identification and characterisation of the strain should include the whole genome sequence.

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 interests: he had a past research activity with the applicant of the products *Pediococcus parvulus* DSM 28875 for all species (EFSA-Q-2016-00236) and *Lactobacillus casei* DSM 28872 for all species (EFSA-Q-2016-00237) (items 5.8 and 5.9). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁹ and the Decision of the Executive Director on Declarations of Interest¹⁰, 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 the items 5.8 and 5.9 by the concerned scientific group.

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

¹⁰ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>