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

Minutes of the 115th Plenary meeting

Held on 20-22 October 2015, Parma (Italy)

(Agreed on 1 December 2015)

Participants

- **Panel Members:**

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

- **Hearing Experts:**

  Andy Hart[2]

- **European Commission and/or Member States representatives:**

  Marta Ponghellini (DG SANTE)[3]

- **EFSA:**

  FEED Unit: Manuela Tiramani, Jaume Galobart, Jaime Aguilera, Montserrat Anguita, Rosella Brozzi, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini, Oriol Ribó and Maria Vittoria Vettori.

  AMU Unit: Elisa Aiassa[4]

- **Others:**

  Not applicable

[1] Present only on 21 and 22 October.
[2] Present only on 22 October for item 7.2.b.
[3] Present only on 21 and 22 October.
[4] Present only on 21 October for item 7.1.a.

1. Welcome and apologies for absence

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

The Chair informed the Panel that María Luisa Fernández-Cruz has resigned from the Panel.

2. Adoption of agenda

The agenda was adopted after the deletion of "L-lysine (Concentrated liquid L-lysine (base), L-lysine monohydrochloride, technically pure, L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum*) for all animal species (EFSA-Q-2011-00991)" and "*Bacillus subtilis* DSM 28343 for chickens for fattening (EFSA-Q-2015-00164)".

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[5] and the Decision of the Executive Director on Declarations of Interest,[6] EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 114th Plenary meeting held on 8-10 September 2015

The minutes of the 114th Plenary meeting were reviewed and agreed.[7]

5. Scientific topics for discussion and/or possible adoption[8]

5.1. Chemically defined flavourings from Chemical Group 05 - Saturated and unsaturated aliphatic secondary alcohols/ketones/ketals/esters with esters containing secondary alcohols. No aromatic or heteroaromatic moiety as a component of an ester or ketal for all animal species and categories (EFSA-Q-2010-01040)

The rapporteur 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

[5] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[6] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[7] http://www.efsa.europa.eu/sites/default/files/event/150908a-m.pdf
[8] During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.

chemically defined flavourings from Chemical Group 05 as sensory additives for all animal species.

The draft opinion was discussed. The Panel concluded that the additives are safe for the target species, the consumer and the environment but expressed concerns for the safety for the users. The Panel also concluded that no demonstration of efficacy was necessary.

The opinion was adopted.[9]

5.2. Ethoxyquin (6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline) for all animal species (EFSA-Q-2010-01224)

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of ethoxyquin as a technological additive for all animal species.

The draft opinion was discussed. The Panel could not conclude on the safety for the target species, consumer and the environment. The additive presents a risk for users. The Panel also concluded that the additive is efficacious but could not confirm the efficacy at the dose proposed.

The opinion was adopted.[10]

5.3. Liderfeed (eugenol) for chickens for fattening (EFSA-Q-2011-00278)

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 Liderfeed as a zootechnical additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumers, users and the environment. However, the Panel could not conclude on the efficacy of the additive.

The opinion was adopted.[11]

5.4. Manganese (manganous chloride tetrahydrate, manganous oxide, manganese sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of glycine hydrate) for all animal species (EFSA-Q-2012-00437)

9 http://www.efsa.europa.eu/en/efsajournal/pub/4268
10 http://www.efsa.europa.eu/en/efsajournal/pub/4272
11 http://www.efsa.europa.eu/en/efsajournal/pub/4273

Not discussed due to lack of time.

5.5. AXTRA® PHY 15000 L (6-phytase) for piglets (weaned), sows for reproduction, pigs for fattening, minor porcine species, chickens for fattening, chickens reared for laying, laying hens, turkeys for breeding purposes, turkeys for fattening, turkeys reared for breeding, minor poultry species (EFSA-Q-2013-00997)

A member of the working group (WG) presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of AXTRA® PHY 15000 L as a zootechnical additive for all pigs and poultry species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumers and environment, but presents risks for the user. The Panel also concluded that the additive is efficacious.

The opinion was adopted.[12]

5.6. L-Arginine produced by *Corynebacterium glutamicum* (KCTC 10423BP) for all animal species (EFSA-Q-2014-00296)

Not discussed due to lack of time.

5.7. Zinc chelate from L-Lysinate HCl (Aminotrace Zinc Bislysinate) for all animal species (EFSA-Q-2014-00496)

A member 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 zinc chelate from L-lysinate HCl as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumers and the environment provided the maximum zinc contents authorised in feed are respected. Concerns arose for users. The Panel also concluded that the additive is an efficacious source of zinc.

The opinion was adopted.[13]

5.8. Sodium selenite (film granulated preparations) for all animal species (EFSA-Q-2014-00508)

12 http://www.efsa.europa.eu/en/efsajournal/pub/4275
13 http://www.efsa.europa.eu/en/efsajournal/pub/4267

A member of the WG presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003 of sodium selenite (film granulated preparations) as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species and is safe for the consumers and the environment provided the maximum selenium contents authorised in feed are respected. Concerns arose for users. The Panel also concluded that the additive is an efficacious source of selenium.

The opinion was adopted.[14]

5.9. AXTRA® XB (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for lactating sows and minor porcine species (EFSA-Q-2014-00574)

Not discussed due to lack of time.

5.10. 036 10 (*Bacillus subtilis* DSM 27273) for weaned piglets and weaned minor porcine species (EFSA-Q-2014-00729)

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 036 10 (*Bacillus subtilis* DSM 27273) as a zootechnical additive for weaned piglets and weaned minor porcine species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumers and the environment. Concerns were expressed for the user. The Panel also concluded that the additive is efficacious.

The opinion was adopted.[15]

5.11. Calsporin® (*Bacillus subtilis* C-3102 (DSM 15544) for Koi carp and ornamental fish (EFSA-Q-2015-00239)

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 Calsporin (*Bacillus subtilis* DSM 15544) as a zootechnical additive for koi carp and ornamental fish.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, consumers and the environment and considered that the extension of use would not introduce concerns to users not already identified in previous assessments. The Panel also concluded that the additive has a

[14] http://www.efsa.europa.eu/en/efsajournal/pub/4271
[15] http://www.efsa.europa.eu/en/efsajournal/pub/4269

potential to improve the growth and feed utilisation of developing ornamental fish.

The opinion was adopted.[16]

5.12. Allura red AC for dogs and cats (EFSA-Q-2015-00286)

A member of the WG presented the question and the draft opinion. The European Commission asked EFSA to deliver an opinion on the safety of Allura red when used as a sensory additive in feed for dogs and cats based on the supplementary information provided by the applicant.

The draft opinion was discussed. The Panel concluded based on the new data that the additive is not genotoxic and derived safe levels for use in feed for dogs and cats.

The opinion was adopted.[17]

5.13. Suilectin (lectins isolated from kidney bean - *Phaseolus vulgaris*) for suckling piglets (EFSA-Q-2015-00314)

The rapporteur presented the question and the draft opinion. The European Commission asked EFSA to deliver an opinion on the efficacy of Suilectin as a zootechnical additive for suckling piglets based on the supplementary information provided by the applicant.

The draft opinion was discussed. The Panel concluded that the additive does not have any effect during the suckling period (0-28 days) but that the proposed use of the additive might have some potential to improve the performance of the piglets during the post-weaning period (28–70 days of age).

The opinion was adopted.[18]

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, who accepted it:

16 http://www.efsa.europa.eu/en/efsajournal/pub/4274
17 http://www.efsa.europa.eu/en/efsajournal/pub/4270
18 http://www.efsa.europa.eu/en/efsajournal/pub/4276

EFSA-Q-Number	Subject
EFSA-Q-2015-00518	Silicic acid, precipitated and dried for all animal species
EFSA-Q-2015-00549	Zinc chelate of methionine hydrate (BIOMET Zn) 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-2015-00429	*Lactobacillus acidophilus* D2/CSL (CECT 4529) for chickens for fattening	21/09/2015
EFSA-Q-2015-00440	Coxipol® (clopidol) for chickens for fattening	22/09/2015

These applications were assigned to the respective working groups.

6.3. Questions under Regulation (EC) No 178/2002 since the previous meeting

EFSA-Q-Number	Subject
EFSA-Q-2015-00555	L-Threonine, technically pure produced by *Escherichia coli* for all animal species
EFSA-Q-2015-00556	L-lysine monohydrochloride produced by fermentation with *Escherichia coli* CGMCC 7.57 for all animal species
EFSA-Q-2015-00557	L-tryptophan, technically pure, produced by *Escherichia coli* CGMCC 7.59 for all animal species

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

7.1. Feedback from EFSA

a) The Panel was informed on the state of the art of the Prometheus (Promoting Methods for evidence use in scientific assessments) project. Deliverable 1 of the project was published in the EFSA website, containing the principles and process for dealing with data and evidence in scientific assessments.[19] Potential needs of support for implementing Prometheus, e.g. templates, guidelines, such as a document explaining the role of WG experts in the production of an opinion or a guidance for protocol development and useful protocol elements, will be discussed at the December plenary meeting.

[19] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4121.pdf

b) Panel members were informed about the training opportunities that EFSA offers to experts.

7.2. Feedback from the Scientific Committee

a) The Vice-Chair of the Panel informed about the topics discussed in the last plenary meeting of the Scientific Committee, in particular, to the adoption of the opinion on the risk profile related to production and consumption of insects as food and feed.

b) A member of the WG on Uncertainty presented the Scientific Committee draft guidance on uncertainty. The FEEDAP Panel has to identify two opinions to be tested in the trial phase. Training on uncertainty and variability will be available for the Panel members.

8. Other scientific topics for information and/or discussion

The Panel was informed about the mandate received by EFSA regarding the assessment on the risk for the development of antimicrobial resistance due to feeding of calves with milk containing residues of antibiotics (EFSA-Q-2015-00611).

9. Any other business

The Panel agreed on extending the next plenary meeting by one day (1-4 December).