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

Minutes of the 117th Plenary meeting

Held on 26-28 January 2016, Parma

(Agreed on 8 March 2016)

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, 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:**

  Not applicable

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

  Not applicable

- **EFSA:**

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

  AMU Unit: Elisa Aiassa[2]

- **Others:**

  Not applicable

[1] Not present on 27 January PM.
[2] Present only on 28 January for item 7.1.a.

1. Welcome and apologies for absence

The Chair welcomed all participants. No apologies were received.

The Chair also welcomed Giovanna Azimonti as a new expert of the Panel. Mrs Azimonti's area of expertise is environmental risk assessment.

2. Adoption of agenda

The agenda was adopted after the deletion of "*Lactobacillus acidophilus* D2/CSL (*Lactobacillus acidophilus* CECT 4529) for chickens for fattening (EFSA-Q-2015-00429)".

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[3] and the Decision of the Executive Director on Declarations of Interest,[4] 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 116th Plenary meeting held on 1-4 December 2015

The minutes of the 116th Plenary meeting were reviewed and agreed.[5]

5. Scientific topics for discussion and/or possible adoption[6,7]

5.1. Chemically defined flavourings from Chemical Group 28 - Pyridine, pyrrole and quinoline derivatives for all animal species and categories (EFSA-Q-2010-01171)

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 chemically defined flavourings from Chemical Group 28 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

[3] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[4] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[5] http://www.efsa.europa.eu/sites/default/files/event/151020a-m.pdf
[6] During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.
[7] For a detailed outcome of the assessment, please refer to the respective opinions published on the EFSA website.

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.[8]

5.2. Chemically defined flavourings from Chemical Group 08 - Secondary alicyclic saturated and unsaturated alcohols/ketones/ketals/esters with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols (EFSA-Q-2010-01181)

Not discussed due to lack of time.

5.3. Chemically defined flavourings from Chemical Group 14 - Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms for all animal species and categories (EFSA-Q-2010-01218)

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 chemically defined flavourings from Chemical Group 14 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]

5.4. Ethyl ester of beta-apo-8'-carotenoic acid for poultry for fattening and poultry for laying (EFSA-Q-2010-01300)

Not discussed due to lack of time.

5.5. Copper complexes of chlorophylls for ornamental fish, grain-eating ornamental birds and small rodents and copper complexes of chlorophyllins for all animal species (EFSA-Q-2010-01524)

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 copper complexes of chlorophylls as a sensory additive for fish,

[8] http://www.efsa.europa.eu/en/efsajournal/pub/4390
[9] http://www.efsa.europa.eu/en/efsajournal/pub/4389

grain-eating ornamental birds and small rodents and of copper complexes of chlorophyllins as a sensory additive for all animal species.

The draft opinion was discussed. In the absence of adequate data, the Panel could not conclude on the safety for the target animals, consumer and user and on the efficacy of the products under assessment. The Panel concluded that the use of additives is safe for the environment.

The opinion was adopted.[10]

5.6. Probiomix B (*Lactobacillus plantarum* KKP/593/p and *Lactobacillus rhamnosus* KKP/825) for chickens for fattening (EFSA-Q-2011-00125)

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 Probiomix B (*Lactobacillus plantarum* KKP/593/p and *Lactobacillus rhamnosus* KKP/825) as a zootechnical additive for chickens for fattening.

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

The opinion was adopted.[11]

5.7. Guanidinoacetic acid (CreAMINO®) for pigs, chickens for fattening and chickens reared for breeding (EFSA-Q-2012-00273)

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 guanidinoacetic acid as a nutritional additive for pigs, chickens for fattening and chickens reared for breeding.

The draft opinion was discussed. The Panel concluded that the additive is safe for chickens for fattening and pigs but could not conclude on the safety for breeders and roosters. The Panel also concluded that the additive is safe for consumers and the environment, and with regards to users, no risk assessment on inhalation toxicity can be reached. The additive is considered efficacious in chickens for fattening but the Panel could not conclude on the efficacy for breeders, roosters and pigs.

The opinion was adopted.[12]

[10] http://www.efsa.europa.eu/en/efsajournal/pub/4391
[11] http://www.efsa.europa.eu/en/efsajournal/pub/4397
[12] http://www.efsa.europa.eu/en/efsajournal/pub/4394

5.8. 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)

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 several manganese compounds as nutritional additives for all animal species.

The draft opinion was discussed. The Panel concluded that all the manganese compounds under application are safe sources of manganese for all animal species/categories, consumers and the environment provided the maximum manganese contents authorised in complete feed are respected; the simultaneous use of manganese compounds via feed and water for drinking should be avoided. Concerns arose for users. The Panel also considered that these compounds are an efficacious source of manganese for animals.

The opinion was adopted.[13]

5.9. Iron (7 forms) for all animal species (EFSA-Q-2012-00491)

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 several iron compounds as nutritional additives for all animal species.

The draft opinion was discussed. The Panel concluded that the additives are safe for the target species at the current maximum EU levels, except for bovines, poultry and pets for which the Panel proposed new (lower) maximum contents. No concerns for the consumer and for the environment safety were identified. Concerns were expressed for user safety. The Panel also concluded that the iron compounds except ferrous carbonate are efficacious sources of iron for all species; ferrous carbonate has the potential to be efficacious on adults only.

The opinion was adopted.[14]

5.10. Ronozyme® Hiphos (6-phytase) for sows for reproduction, sows in order to have benefit in piglets and fish (salmonids, sea bream, tilapia) (EFSA-Q-2014-00289)

[13] http://www.efsa.europa.eu/en/efsajournal/pub/4395
[14] http://www.efsa.europa.eu/en/efsajournal/pub/4396

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the modification of the terms of authorisation under Article 13 of Regulation (EC) No 1831/2003 of Ronozyme® Hiphos (6-phytase) as a zootechnical additive for sows for reproduction, sows in order to have benefit in piglets and fish (salmonids, sea bream, tilapia).

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, is efficacious in sows, but could not conclude on the efficacy for fish.

The opinion was adopted.[15]

5.11. Ronozyme® NP (6-phytase) for pigs for fattening (EFSA-Q-2014-00450)

A member of the working group presented the question and the draft opinion. This question refers to the modification of the terms of authorisation under Article 13 of Regulation (EC) No 1831/2003 of Ronozyme® NP (6-phytase) as a zootechnical additive for pigs for fattening.

The draft opinion was discussed. The Panel concluded that the proposed modifications would not affect the safety of the additive already assessed. The Panel could not conclude on the efficacy of the product at the newly proposed minimum recommended dose.

The opinion was adopted.[16]

5.12. Sodium selenite (Retosel 100 sd) for all animal species (EFSA-Q-2014-00505)

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 sodium selenite 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; it 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.[17]

6. New mandates

6.1. New applications under Regulation (EC) No 1831/2003 since the previous meeting

[15] http://www.efsa.europa.eu/en/efsajournal/pub/4393
[16] http://www.efsa.europa.eu/en/efsajournal/pub/4392
[17] http://www.efsa.europa.eu/en/efsajournal/pub/4398

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:

EFSA-Q-Number	Subject
EFSA-Q-2015-00767	Citranaxanthin (Lucantin CX® forte) for laying hens
EFSA-Q-2015-00766	Sodium Molybdate, dehydrate for all animal species
EFSA-Q-2015-00834	Hostazym (endo-1,4-beta xylanase) for chickens reared for laying, minor poultry species reared for laying
EFSA-Q-2016-00075	AXTRA® PHY 20000 TPT (20000 FTU/g 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-2016-00076	Nimicoat (carvacrol) for piglets (weaned)
EFSA-Q-2016-00074	L-Threonine for all animal species
EFSA-Q-2016-00078	Phyllite, natural mixture of minerals of metamorphic origin. Minimum content of phyllo-, and alumo-/alumohydrosilicates like muscovite, illite, chlorite and talc ≥ 40% (by mass) for all animal species
EFSA-Q-2015-00767	Citranaxanthin (Lucantin CX® forte) for laying hens
EFSA-Q-2015-00766	Sodium Molybdate, dehydrate 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-2015-00615	Rovabio® Spiky (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for all poultry species (major and minor)	07/12/2015
EFSA-Q-2015-00616	Coxiril® (diclazuril) for chickens reared for laying	07/12/2015
EFSA-Q-2015-00482	Preparation of 3-phytase (EC 3.1.3.8.) produced by fermentation of a genetically modified strain of *Pichia pastoris* (strain ATCC 76273/CBS 7435/ CECT 11047) for chickens for fattening and laying hens	11/12/2015
EFSA-Q-2015-00549	Zinc chelate of methionine hydrate (BIOMET Zn) for all animal species	18/12/2015
EFSA-Q-2015-00724	*Lactobacillus diolivorans* DSM 32074 for all animal species	06/01/2016
EFSA-Q-2015-00732	Natuphos® E 5000 G; Natuphos® E 10000 G (6-phytase) for all pigs and all avian species	07/01/2016

EFSA-Q-2015-00626	*Lactobacillus rhamnosus* DSM 29226 for all animal species	21/01/2016
EFSA-Q-2015-00627	*Lactobacillus plantarum* DSM 29024 for all animal species	21/01/2016
EFSA-Q-2015-00652	*Lactobacillus plantarum* DSM 29025 for all animal species	21/01/2016

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-2016-00069	Guidance Document for the Risk Assessment of additives produced with Genetically Modified Microorganisms
EFSA-Q-2016-00068	Analysis of the need for an update of the guidance documents
EFSA-Q-2016-00070	Consultation of the European Food Safety Authority under Article 7(4) and (5) of Regulation (EC) No 1831/2003 on the amendment of Commission Regulation (EC) No 429/2008

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

7.1. Feedback from EFSA

a) In the framework of the Prometheus (Promoting Methods for evidence use in scientific assessments) project, the Panel reviewed the answers provided to the survey and discussed a consolidated panel position on the different questions.

b) The Panel was informed on the trainings that EFSA is offering, especially on the area of uncertainty and variability.

c) The Chair also informed the Panel on the joint session with the ANS Panel that will take place during the next plenary meeting.

8. Other scientific topics for information and/or discussion

a) The Panel was informed about a letter received from an applicant regarding a recently adopted opinion on an amino acid, in which the Panel could not conclude on the safety of most of the products subject to the application. The applicant objected to the conclusions of the opinion for some of the products, raising arguments to substantiate the objections.

Discussion took place about each of the arguments raised in the letter. The Panel concluded that none of the arguments would trigger the need to revise the adopted opinion.

b) The Panel was informed that the Executive Director of EFSA has accepted the proposal for the self-task to develop an up-to-date

guidance document for the assessment of additives produced with genetically modified microorganisms. The deadline to deliver this guidance is 30 September 2017. The draft Guidance Document will be developed by the FEEDAP Panel WG on Genetically Modified Microorganisms.

c) The Executive Director also accepted the self-task to revise and update the different guidance documents adopted by the Panel regarding the assessment of feed additives. The deadline to finalise this task is 30 June 2018. A standing working group will be established for this task. The Panel was also informed on the work plan for this self-task.

9. Any other business

a) Discussion took place regarding the working methods of the Panel, especially the revision of opinions before the plenary.