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

Minutes of the 119th Plenary meeting

Held on 19-21 April 2016, Parma

(Agreed on 24 May 2016)

Participants

- **Panel Members:**

  Giovanna Azimonti,[1] Maria de Lourdes Bastos, Andrew Chesson, Pier Sandro Cocconcelli, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Secundino López Puente, Marta López-Alonso, Alberto Mantovani,[2] 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:**

  Marta Ponghellini (DG SANTE)

- **EFSA:**

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

- **Others:**

  Not applicable

1. Welcome and apologies for absence

The Chair welcomed all participants. Apologies were received from Gabriele Aquilina, Vasileios Bampidis, Georges Bories and Baltasar Mayo.

[1] Not present on 21 April.
[2] Not present on 19 April AM.

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 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 118th Plenary meeting held on 8-10 March 2016

The minutes of the 118th 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 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)

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 08 as sensory additives for all animal species.

The opinion was originally adopted in the last plenary in March, but some issues were identified in the assessment of the safety for one of the compounds (methyl 3-oxo-2-pentyl-1-cyclopentylacetate). In particular, in the original assessment, the FEEDAP Panel did not assess a 90-day oral toxicity study in rats with this compound, and based the conclusion on the safety for target species on the threshold of toxicological concern. As this omission had an implication in the conclusions on the safety, the FEEDAP Panel agreed to withdraw 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/160308a-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.

adopted opinion. A new updated draft was presented for discussion in which the safety assessment of this compound was based on the results of the 90-day toxicity study. The Panel concluded that the additives are safe for the target species, the consumer and expressed concerns for the safety for the users and the environment. The Panel also concluded that no demonstration of efficacy was necessary.

The opinion was adopted.

5.2. Iron oxide yellow, iron oxide black and iron oxide red for all animal species (EFSA-Q-2010-01274, EFSA-Q-2010-01291 and EFSA-Q-2010-01292)

The rapporteur presented the questions and the draft opinion. These questions refer to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Iron oxide yellow, iron oxide black and iron oxide red as sensory additives for all animal species.

The draft opinion was discussed. In the absence of adequate toxicological data, the Panel could not conclude on the safety of these additives for the target species. Use of these compounds in animal nutrition is considered safe for consumers and the environment, but the Panel expressed concerns for the safety for users. The additives are efficacious in colouring feedingstuffs.

The opinion was adopted.

5.3. Diarr-Stop S Plus® (Na_2EDTA, *Castanea sativa*, thyme oil, oregano oil) for pigs for fattening (EFSA-Q-2011-00060)

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 Diarr-Stop S Plus® (Na_2EDTA, *Castanea sativa*, thyme oil, oregano oil) as a zootechnical additive for pigs for fattening.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species and consumers, but some concerns were expressed for user safety. Based on the data provided, the Panel could not conclude on the safety for the environment and on the efficacy of the additive.

The opinion was adopted.[8]

[8] http://www.efsa.europa.eu/en/efsajournal/pub/4472

5.4. Manganese hydroxychloride (IntelliBond® M) for all animal species (EFSA-Q-2013-00406)

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 manganese hydroxychloride 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. No conclusion on the safety for users could be reached. The Panel also concluded that the additive is an efficacious source of manganese.

The opinion was adopted.[9]

5.5. Bactocell PA or Fermaid PA (*Pediococcus acidilactici* (CNCM MA 18/5M) for pigs for fattening and chickens for fattening (EFSA-Q-2014-00091) and Bactocell (PA 10) and Bactocell (PA 10) MA (*Pediococcus acidilactici* (CNCM MA 18/5M) for minor avian and minor porcine species (EFSA-Q-2013-00704)

The rapporteur presented the questions and the draft opinion. These questions refer to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Bactocell PA (*Pediococcus acidilactici* CNCM MA 18/5M) as a zootechnical additive for pigs for fattening and chickens for fattening and for minor avian and porcine species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target animals, consumers and the environment. Concerns for users are limited to respiratory sensitisation. The Panel also concluded that the additive has the potential to be efficacious and that the active agent is compatible with some coccidiostats.

The opinion was adopted.

5.6. Dry grape extract for all animal species (EFSA-Q-2014-00213)

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 dry grape extract as a sensory additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species (except for dogs, for which a

[9] http://www.efsa.europa.eu/en/efsajournal/pub/4474

safe concentration could not be derived), consumers and the environment. No conclusion on the safety for users could be reached. The Panel also concluded that no demonstration of efficacy was necessary.

The opinion was adopted.

5.7. Levucell SB 20/SB 10 ME/Titan (*Saccharomyces cerevisiae* CNCM I-1079) for piglets (weaned) and sows in order to have benefit in piglets (EFSA-Q-2014-00227)

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 Levucell (*Saccharomyces cerevisiae* CNCM I-1079) as a zootechnical additive for piglets and sows.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target animals, consumers, users and the environment. The Panel also concluded that the additive has the potential to be efficacious.

The opinion was adopted.

5.8. L-Threonine technically pure produced by fermentation with *Escherichia coli* CGMCC 7.58 for all animal species (EFSA-Q-2015-00555)

The rapporteur presented the question and the draft opinion. EFSA has been asked to deliver an opinion on the safety of L-threonine produced by *Escherichia coli* CGMCC 7.58 when used as a nutritional additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. The Panel concluded that the genetic modification does not raise concerns for the safety for the target species, consumers, users and the environment. However, the levels of endotoxins and the dusting potential represent a health risk for the user upon inhalation and the additive should be considered a potential dermal sensitiser.

The opinion was adopted.[10]

5.9. L-lysine monohydrochloride produced by fermentation with *Escherichia coli* CGMCC 7.57 for all animal species (EFSA-Q-2015-00556)

The Chair of the working group (WG) presented the question and the draft opinion. EFSA has been asked to deliver an opinion on the safety of L-lysine monohydrochloride produced by *Escherichia coli*

[10] http://www.efsa.europa.eu/en/efsajournal/pub/4470

CGMCC 7.57 when used as a nutritional additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. The Panel concluded that the genetic modification does not raise concerns for the safety for the target species, consumers, users and the environment. The levels of endotoxins present in the product and its dusting potential indicate no health risk for the user

The opinion was adopted.[11]

5.10. *Lactobacillus rhamnosus* DSM 29226 for all animal species (EFSA-Q-2015-00626)

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 rhamnosus* DSM 29226 as a technological additive for all animal species.

The draft opinion was discussed. The Panel identified the need to request additional information to the applicant in order to finalise the opinion. The applicant will be requested to provide additional information.

5.11. *Lactobacillus plantarum* DSM 29024 for all animal species (EFSA-Q-2015-00627)

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 plantarum* DSM 29024 as a technological additive for all animal species.

The draft opinion was discussed. The Panel identified the need to request additional information to the applicant in order to finalise the opinion. The applicant will be requested to provide additional information.

5.12. *Lactobacillus plantarum* DSM 29025 for all animal species (EFSA-Q-2015-00652)

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 plantarum* DSM 29025 as a technological 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, but could not conclude on the safety for users. The Panel also concluded that the additive is efficacious.

[11] http://www.efsa.europa.eu/en/efsajournal/pub/4471

The opinion was adopted.

5.13. Lancer (Lanthanide-citrate) for weaned piglets (EFSA-Q-2015-00718)

A member of the WG presented the question and the draft opinion. EFSA has been asked to deliver an opinion on the safety of Lancer (lanthanide citrate) when used as a zootechnical additive for weaned piglets based on the supplementary information provided by the applicant.

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

The opinion was adopted.[12]

5.14. Analysis of the need for an update of the guidance documents (EFSA-Q-2016-00068)

The Chair of the WG presented the questions and the draft statement. This question refers to the self-task of the Panel on the revision of the guidance documents.

The draft statement was discussed. The Panel identified which broad areas in the existing guidance documents need to be revised. The Panel proposed the revision/update of most of the guidance documents and set a priority list.

The statement was adopted.[13] The Panel will seek input from the interested stakeholders on the proposal for the revision of the different guidance documents. This statement will be the basis for the discussion in the future info-session with stakeholders that will take place in July 2016.

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:

EFSA-Q-Number	Subject
EFSA-Q-2016-00196	Activo® MC (Encapsulated mixture of secondary plant compounds with carvacrol as marker compound) for all avian species, pigs for fattening

[12] http://www.efsa.europa.eu/en/efsajournal/pub/4477
[13] http://www.efsa.europa.eu/en/efsajournal/pub/4473

EFSA-Q-2016-00197	Calsporin® (*Bacillus subtilis* C-3102 (DSM 15544)) for pigs for fattening
EFSA-Q-2016-00215	Fermentation product of *Aspergillus oryzae* DSM 23104 for chickens for fattening
EFSA-Q-2016-00236	*Pediococcus parvulus* DSM 28875 for all animal species
EFSA-Q-2016-00237	*Lactobacillus casei* DSM 28872 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-2015-00618	Coxar® (nicarbazin) for turkeys for fattening	07/03/2016
EFSA-Q-2016-00112	Natural essential oil from *Origanum vulgare* L. ssp. *hirtum* var. Vulkan (DOS 00001) for all animal species	14/03/2016
EFSA-Q-2015-00767	Citranaxanthin (Lucantin CX® forte) for laying hens	18/03/2016
EFSA-Q-2016-00090	Actisaf® Sc 47 (*Saccharomyces cerevisiae* NCYC Sc 47/CNCM I-4407) for fattening lambs	11/04/2016
EFSA-Q-2016-00137	Actisaf® Sc 47 (*Saccharomyces cerevisiae* NCYC Sc 47) for cattle for fattening, dairy cows, piglets (weaned), sows	11/04/2016
EFSA-Q-2016-00138	Organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 (Selenised yeast inactivated) (SEL-PEX) for all animal species	11/04/2016
EFSA-Q-2016-00089	Calsporin® (*Bacillus subtilis* C-3102 (DSM 15544) for chickens for fattening	11/04/2016
EFSA-Q-2016-00088	Alkosel 3000 (Selenium enriched yeast (*Saccharomyces cerevisiae* NCYC R397)) for all animal species	12/04/2016

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-2016-00130	*Saccharomyces cerevisiae* NBRC 0203, *Lactobacillus plantarum* NBRC 3070 and *Lactobacillus casei* NBRC 3425 (EM-silage)
EFSA-Q-2016-00220	*Bacillus subtilis* GR-101 and *Aspergillus oryzae* GB-107 for all animal species
EFSA-Q-2016-00267	Ethoxyquin 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 updated on the organisation of the open plenary and info session that will take place in July 2016 in Brussels.

b) The Head of Unit informed the Panel on the organisation of the meetings for the second half of the year.

c) The Panel was also informed on the recent developments on the application of the principles of the Scientific Committee's guidance on uncertainty.

8. Other scientific topics for information and/or discussion

a) The WG on Technological additives requested advice to the Panel on the assessment of the genotoxicity potential of ethoxyquin quinone imine, a metabolite/impurity of the feed additive ethoxyquin. The Panel agreed to request assistance to the Scientific Committee's WG on genotoxicity.

b) The Panel discussed on the acceptability of studies in the target species in which the animals were treated with antibiotics/antimicrobials either before the start or during the course of the study. As mentioned in Regulation (EC) No 429/2008 and the guidance documents, any of such treatments should be recorded and reported in the experimental studies. The Panel noted that the studies in which the animals receive antimicrobials during the whole experimental period are not acceptable.

The Panel considers that as a principle, animals used in the studies should be healthy. However, in certain occasions preventive treatments with antibiotics/antimicrobials are applied before the start of the trial. The Panel considers that this practice should not be encouraged. The acceptability of such trials will depend on whether the end-points measured would be affected by the treatment.

The acceptability of trials in which animals are treated with antibiotics/antimicrobials during the course of the study will depend also on the number of animals treated, duration of the treatment, distribution between experimental groups and severity of the disease, among other factors. The acceptability of these studies will be assessed on a case by case basis.

c) An initial discussion took place on the application of an additional uncertainty factor (UF) of 5 in the assessment of the safety of flavouring compounds for cats. Cats and feline species have a reduced capacity for glucuronidation compared to other species. Since 2012, the additional UF has been consistently applied in flavourings opinions where glucuronidation is a major

metabolic pathway. The scientific rationale for selecting an UF of 5 for cats needs further discussion in a future meeting.

d) The Panel noted that the tables on default values for feed intake present in the guidance on sensory additives[14] and the guidance on additives already authorised for use in food[15] are not accurate. In fact, for cattle for fattening, dairy cows, cats and dogs, the feed intake (as g/day) is expressed as dry matter (DM), whereas for the other species, the feed intake is expressed as a feed containing 88% DM, except milk replacer for veal calves (94.5% DM). The tables in these guidance documents are missing the explanatory footnotes for this fact. Although this issue was identified in July 2013, the Panel acknowledges that it was not made public in the minutes of the Panel nor corrected in the above guidance documents. The Panel will consider this in the upcoming update of the guidance documents. The corrected table which is currently being used by the Panel is reproduced below.

Target animal	**Default values**	
	Body weight (kg)	**Feed intake (g/day)(1)**
Salmonids	2	40
Veal calves (milk replacer)	100	2,000
Cattle for fattening	400	8,000
Dairy Cows	650	20,000
Piglets	20	1,000
Pigs for fattening	100	3,000
Sows	200	6,000
Chickens for fattening	2	120
Laying hens	2	120
Turkeys for fattening	12	400
Dogs	15	250
Cats	3	60

(1): Complete feed with 88% dry matter (DM), except milk replacer for veal calves (94.5% DM), and for cattle for fattening, dairy cows, dogs and cats for which the values are DM intake.

9. Any other business

Not discussed

[14] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2534.pdf
[15] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2538.pdf