

SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

MINUTES OF THE 146th FEEDAP PLENARY MEETING

Webconference, 07 May 2020

(Agreed by written procedure on 13 May 2020)

Participants

■ **Panel Members:**

Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Kos Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Roberto Edoardo Villa and Ruud Woutersen.

■ **Hearing Experts:**

Not applicable

■ **European Commission**

Marta Ponghellini (DG SANTE)

■ **EFSA:**

Feed Unit: Angelica Amaduzzi, Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Yolanda García Cazorla, Lucilla Gregoretti, Davide Guerra, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini, Elisa Pettenati, Fabiola Pizzo, Konstantinos Sofianidis, Jordi Tarrés-Call, Frank Verdonck and Maria Vittoria Vettori.

■ **Others:**

Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Yolanda Sanz.

This meeting, originally scheduled as a physical meeting, was converted into a webconference to avoid traveling to Parma in line with the measures established to reduce the risk of coronavirus infection.

2. Adoption of agenda

The agenda was adopted without modifications.



3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Report on written procedures since the 144th FEEDAP Plenary meeting

The minutes of the 145th FEEDAP Plenary meeting were agreed by written procedure on 26 March 2020³.

The opinion on Montmorillonite-Illite for all animal species (EFSA-Q-2019-00334) was adopted during the last plenary meeting on 20 March 2020. The Panel withdrew the adoption of the opinion on 22 April 2020 (before its publication) by written procedure since some information submitted by the applicant had not been taken into consideration in the assessment due to a clerical mistake. This opinion has been included in the agenda of the present plenary.

5. Scientific topics for discussion

5.1. Perlite for ruminants and poultry ([EFSA-Q-2014-00457](#))

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of perlite as a technological additive for ruminants and poultry.

Given the amount of information missing from the dossier, the Panel is not able to perform an assessment of this application. The Panel unanimously adopted the statement.

5.2. ProEquo® (*Lactobacillus plantarum* DSM 11520) for horses ([EFSA-Q-2017-00023](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of ProEquo® (*Lactobacillus plantarum* DSM 11520) as a zootechnical additive for horses.

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The Panel unanimously adopted the opinion.

5.3. Botanically defined flavourings from Botanical Group 09 - Zingiberales for all animal species and categories: turmeric oil, turmeric oleoresin, turmeric extract (sb) and turmeric tincture from *Curcuma longa* L. ([EFSA-Q-2017-00532](#))

This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Botanically defined flavourings from Botanical Group 09 - Zingiberales: turmeric oil, turmeric oleoresin, turmeric extract (sb) and turmeric tincture from *Curcuma longa* L. as sensory additives for all animal species.

The draft opinion was discussed focusing mainly on the characterisation, safety and efficacy of the additive. The Panel unanimously adopted the opinion.

¹ [Policy on Independence](#)

² [Competing Interest Management](#)

³ <http://www.efsa.europa.eu/sites/default/files/event/2020/145th-plenary-meeting-feedap-panel-minutes.pdf>



5.4. Botanically defined flavourings from Botanical Group 09 – Zingiberales for all animal species and categories: ginger oil, ginger oleoresin, ginger tincture and ginger extract from *Zingiber officinale* Rosc (EFSA-Q-2017-00533)

This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Botanically defined flavourings from Botanical Group 09 - Zingiberales: ginger oil, ginger oleoresin, ginger tincture and ginger extract from *Zingiber officinale* Rosc as sensory additives for all animal species.

The draft opinion had been discussed in the previous plenary. The Panel unanimously adopted the opinion.

5.5. STABILFLOR® (mixture of ZnEDTA and Cu(NH₄)₂EDTA chelates, on chicory pulp carrier, supplemented with 3bE6 ZnO and 3bE4 CuO) for pigs (EFSA-Q-2017-00627)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of STABILFLOR® as a zootechnical additive for pigs.

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The Panel unanimously adopted the opinion.

5.6. Selenium enriched yeast (*Saccharomyces cerevisiae* CNCM I-3399) for all animal species (EFSA-Q-2018-00908)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of selenium enriched yeast (*Saccharomyces cerevisiae* CNCM I-3399) as a nutritional additive for all animal species.

The draft opinion was discussed focusing mainly on the characterisation and safety of the additive. The Panel unanimously adopted the opinion.

5.7. IMP (disodium 5'-inosinate) produced by fermentation with *Corynebacterium ammoniagenes* KCCM 80161 for all animal species (EFSA-Q-2019-00040)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of IMP (disodium 5'-inosinate) produced by fermentation with *Corynebacterium ammoniagenes* KCCM 80161 as a sensory additive for all animal species.

The draft opinion was discussed focusing mainly on the characterisation, safety and efficacy of the additive. The Panel unanimously adopted the opinion.

5.8. OptiPhos® PLUS (6-phytase) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening, minor poultry species reared for laying, minor poultry species reared for breeding and ornamental birds (EFSA-Q-2019-00303)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of OptiPhos® PLUS (6-phytase) as a zootechnical additive for poultry species for fattening and reared for laying/breeding and ornamental birds.

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The Panel unanimously adopted the opinion.



5.9. Montmorillonite-Illite for all animal species ([EFSA-Q-2019-00334](#))

This question refers to the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of montmorillonite-illite as a technological additive for all animal species.

The draft opinion was originally adopted in March 2020. However, after adoption it was identified that due to a clerical mistake, some information spontaneously submitted by the applicant had not been made available to the Panel at the time of the adoption. Therefore, the Panel decided to withdraw the adoption of the opinion on 22/04/2020 (before it was published). The missing information has now been assessed and the updated opinion submitted to the panel for evaluation.

The draft opinion was discussed focusing mainly on the new information regarding efficacy. The Panel unanimously adopted the opinion.

5.10. APSA PHYTAFEED® 20,000 GR, APSA PHYTAFEED® 20,000 L (6-phytase) for laying hens and other laying birds ([EFSA-Q-2019-00461](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of APSA PHYTAFEED® 20,000 GR, APSA PHYTAFEED® 20,000 L (6-phytase) as a zootechnical additive for laying hens and other laying birds.

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The Panel unanimously adopted the opinion.

5.11. Calcium formate for all animal species ([EFSA-Q-2020-00230](#))

EFSA was requested to deliver an opinion on the safety of calcium formate as a technological additive for all animal species based on the additional information provided by the applicant.

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

5.12. Sodium formate for all animal species ([EFSA-Q-2020-00258](#))

EFSA was requested to deliver an opinion on the safety of sodium formate as a technological additive for all animal species based on the additional information provided by the applicant.

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



6. New mandates

6.1. New Applications under Regulation (EC) 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-2020-00212	Zinc chelate of amino acids hydrate (Availa® Zn) for all animal species
EFSA-Q-2020-00267	GMP (disodium 5'-guanylate) produced by fermentation with <i>Corynebacterium ammoniagenes</i> KCCM 10530 and <i>Escherichia coli</i> K12 KFCC 11067 for all animal species
EFSA-Q-2020-00273	L-threonine for all animal species
EFSA-Q-2020-00279	<i>Lactobacillus plantarum</i> DSM 26571 for all animal species
EFSA-Q-2020-00281	Lactic acid for all animal species
EFSA-Q-2020-00282	Sacox® (salinomycin sodium) for rabbits for fattening
EFSA-Q-2020-00290	Allura Red for small mammals and ornamental birds
EFSA-Q-2020-00313	Biosprint® (<i>Saccharomyces cerevisiae</i> MUCL 39885) for piglets (weaned)
EFSA-Q-2020-00323	Vitamin B ₂ (Riboflavin produced by <i>Eremothecium ashbyii</i> CCTCCM 2019833) for all animal species
EFSA-Q-2020-00325	Pyridoxine hydrochloride for all animal species
EFSA-Q-2020-00326	L-lysine monohydrochloride and concentrated liquid L-lysine (base) produced by fermentation with <i>Corynebacterium glutamicum</i> KCTC 12307BP (C123) 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-2019-00768	Nicarb® (nicarbazin) for chickens for fattening	09/03/2020
EFSA-Q-2020-00004	Beltherm MP and Beltherm ML (endo-1,4-beta-xylanase) (IUB:EC 3.2.1.8) for laying hens, minor poultry species, all avian species	29/04/2020
EFSA-Q-2020-00005	Vitamin E/all-rac-alpha tocopherol acetate for all animal species	03/04/2020
EFSA-Q-2020-00007	L-isoleucine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80185 for all animal species	02/04/2020



EFSA-Q-Number	Subject	Valid on
EFSA-Q-2020-00146	Vitamin E / all-rac-alpha tocopheryl acetate (3a700) for all animal species	28/04/2020
EFSA-Q-2020-00147	ROVABIO® ADVANCE powder & liquid (Endo-1,4-beta-xylanase (EC 3.2.1.8), Endo-1,3(4)-beta-glucanase (EC 3.2.1.6)) for pigs for fattening, piglets (weaned)	24/03/2020
EFSA-Q-2020-00148	Vitamin E/all-rac-alpha tocopheryl acetate for all animal species	25/03/2020
EFSA-Q-2020-00156	RRR alpha tocopheryl acetate for all animal species	27/04/2020
EFSA-Q-2020-00160	Vitamin B ₂ (riboflavin) for all animal species	05/05/2020
EFSA-Q-2020-00169	Plexomin® L-Fe (Ferrous lysinate sulfate) for all animal species	11/03/2020
EFSA-Q-2020-00189	L-histidine monohydrochloride monohydrate produced by fermentation with <i>Escherichia coli</i> K-12 KCCM 80212 (H010) for all animal species	16/04/2020
EFSA-Q-2020-00199	Balancius (muramidase) for piglets (weaned)	20/04/2020
EFSA-Q-2020-00201	Clinacox 0.5% (contains 0.5 g diclazuril per 100 g) for chickens for fattening	22/04/2020
EFSA-Q-2020-00203	Clinacox 0.5% (contains 0.5 g diclazuril per 100 g) for chickens reared for laying	22/04/2020

These applications were assigned to the respective working groups, where relevant.

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

EFSA-Q-Number	Subject
EFSA-Q-2020-00251	Preparation of 3-phytase (EC 3.1.3.8) produced by <i>Pichia pastoris</i> (ATCC 76273 / CBS 7435 / CECT 11047) FLF1000
EFSA-Q-2020-00256	L-tryptophan produced by <i>Escherichia coli</i> CGMCC 11674 for all animal species
EFSA-Q-2020-00258	Sodium formate (E 237) for all animal species
EFSA-Q-2020-00280	<i>Bacillus licheniformis</i> ENV01 / DSM 32457 (Optimize) for all animal species
EFSA-Q-2020-00310	Manganese chelates of lysine and glutamic acid (ProPath Mn) for all animal species
EFSA-Q-2020-00324	Deccox® (E756) for chickens for fattening

These questions were assigned to the respective working groups, where relevant.



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

7.1. Scientific Committee/Scientific Panels

The Panel was informed on the upcoming EFSA Scientific Panels' consultation on the draft statement from the Scientific Committee on the derivation of Health-Based Guidance Values (HBGV) for regulated products that are also nutrients.

7.2. EFSA

Not discussed.

7.3. European Commission

Not discussed.

8. Other scientific topics for information/or discussion

- a) The Panel was informed that recently a discussion took place in the working group on animal nutrition regarding the compliance of tolerance and efficacy studies in target species with the provisions of Directive 63/2010/EU on the protection of animals used for scientific purposes. The Guidance on the safety for the target species and the Guidance on the assessment of the efficacy of feed additives both require that "Studies should be performed and documented according to appropriate quality standards and should respect the rules on animal welfare laid down by EU legislation, particularly those listed in Directive 63/2010/EU". This compliance should be clearly indicated/reported in the report of the studies by i) the ethical statement, indicating compliance with relevant guidelines for the care and use of animals, ii) housing and husbandry conditions in which the animals were kept during the study and iii) experimental procedures followed during the study. The Panel wishes also to raise the attention of applicants on the compliance and reporting on these aspects in the study reports sent for assessment.

9. Any other business

Not discussed.