



FEED UNIT

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

MINUTES OF THE 157th FEEDAP PLENARY MEETING

Webconference, 29-30 September 2021

(Agreed by written procedure on 6 October 2021)

Participants

■ Panel Members:

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

■ Hearing Experts:

Jürgen Gropp¹

■ European Commission

Not applicable

■ EFSA:

Feed Unit: Angelica Amaduzzi, Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Lucilla Gregoret, Davide Guerra, Matteo Lorenzo Innocenti, Paola Manini, Jordi Ortuño, Elisa Pettenati, Fabiola Pizzo, Daniel Plaza, Anita Radovnikovic, Martina Reitano, Joana Revez, Jordi Tarrés-Call, Frank Verdonck and Maria Vittoria Vettori.

SCER Unit: José Tarazona²

REPRO Department: Guilhem de Seze³

■ Others:

Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

¹ Present only on 30 September for item 5.5

² Present only on 29 September for item 7.1.b

³ Present only on 30 September for item 7.2



2. Adoption of agenda

The agenda was adopted after deletion of the topic on "Sodium aluminosilicate, synthetic for all animal species ([EFSA-Q-2019-00661](#))".

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, 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 156th FEEDAP Plenary meeting

The minutes of the 156th FEEDAP Plenary meeting were agreed by written procedure on 10 September 2021⁶.

5. Scientific topics for discussion

5.1. **Botanically defined flavourings from Botanical Group 06 - Laurales, Magnoliales, Piperales for all animal species and categories: camphor white oil** ([EFSA-Q-2010-01296](#), [EFSA-Q-2021-00514](#))

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of camphor white oil as a sensory additive for all animal species.

The draft opinion was discussed and the Panel identified the need for further discussion. The opinion will be discussed again in the next Plenary meeting.

5.2. **Botanically defined flavourings from Botanical Group 08 - Sapindales for all animal species and categories: expressed orange oil and its fractions for all animal species** ([EFSA-Q-2010-01517](#), [EFSA-Q-2021-00146](#))

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of expressed orange oil and its fractions as a sensory additive for all animal species.

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

5.3. **Cashew nutshell liquid for all animal species** ([EFSA-Q-2016-00314](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of cashew nutshell liquid as a technological additive for all animal species.

⁴ [Policy on Independence](#)

⁵ [Competing Interest Management](#)

⁶ https://www.efsa.europa.eu/sites/default/files/2021-09/feedap20210907_m.pdf



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

5.4. Lemon extract for all animal species ([EFSA-Q-2018-00680](#))

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of lemon extract as a sensory additive for all animal species.

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

5.5. Bovaer® 10 (3-nitrooxypropanol) for dairy cows for milk production, cows for reproduction, dairy sheep for milk production, ewes for reproduction, dairy goats for milk production, goats for reproduction, other ruminants for milk production and other ruminants for reproduction ([EFSA-Q-2019-00592](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Bovaer® 10 (3-nitrooxypropanol) as a zootechnical additive for dairy cows for milk production, cows for reproduction, dairy sheep for milk production, ewes for reproduction, dairy goats for milk production, goats for reproduction, other ruminants for milk production and other ruminants for reproduction.

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

5.6. Beltherm MP and Beltherm ML (endo-1,4-beta-xylanase) (IUB:EC 3.2.1.8) for laying hens, minor poultry species and all avian species ([EFSA-Q-2020-00004](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Beltherm MP and Beltherm ML (endo-1,4-beta-xylanase) (IUB:EC 3.2.1.8) as a zootechnical additive for laying hens, minor poultry species and all avian species.

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

5.7. Iron chelate of amino acids hydrate for all animal species ([EFSA-Q-2020-00174](#))

This question refers to the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of iron chelate of amino acids hydrate as a nutritional additive for all animal species.

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

5.8. Manganese chelate of amino acids hydrate for all animal species ([EFSA-Q-2020-00181](#))

This question refers to the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of manganese chelate of amino acids hydrate as a nutritional additive for all animal species.

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



5.9. Copper chelate of amino acids hydrate for all animal species ([EFSA-Q-2020-00182](#))

This question refers to the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of copper chelate of amino acids hydrate as a nutritional additive for all animal species.

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

5.10. Preparation of *Bacillus subtilis* CNCM I-4606, *Bacillus subtilis* CNCM I-5043, *Bacillus subtilis* CNCM I-4607 and *Lactococcus lactis* CNCM I-4609 for all animal species ([EFSA-Q-2020-00202](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of preparation of *Bacillus subtilis* CNCM I-4606, *Bacillus subtilis* CNCM I-5043, *Bacillus subtilis* CNCM I-4607 and *Lactococcus lactis* CNCM I-4609 as a technological additive for all animal species.

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

5.11. Zinc chelate of amino acids hydrate for all animal species ([EFSA-Q-2020-00212](#))

This question refers to the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of zinc chelate of amino acids hydrate as a nutritional additive for all animal species.

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

5.12. *Lactobacillus plantarum* DSM 26571 for all animal species ([EFSA-Q-2020-00279](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Lactobacillus plantarum* DSM 26571 as a technological additive for all animal species.

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

5.13. Protural Granular, Protural Powder (sodium benzoate) for weaned piglets and other growing suidae ([EFSA-Q-2020-00462](#))

This question refers to the authorisation under Article 4 and the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Protural Granular, Protural Powder (sodium benzoate) as a zootechnical additive for weaned piglets and other growing suidae.

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

5.14. *Lactobacillus brevis* DSM 12835 for all animal species ([EFSA-Q-2020-00691](#))

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Lactobacillus brevis* DSM 12835 as a technological additive for all animal species.



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

5.15. *Lactobacillus rhamnosus* NCIMB 30121 for all animal species ([EFSA-Q-2020-00706](#))

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Lactobacillus rhamnosus* NCIMB 30121 as a technological additive for all animal species.

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

5.16. *Lactobacillus paracasei* DSM 16245 for all animal species ([EFSA-Q-2020-00707](#))

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Lactobacillus paracasei* DSM 16245 as a technological additive for all animal species.

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

5.17. Calsporin® (preparation of *Bacillus velezensis* (formerly *Bacillus subtilis*) DSM 15544) for piglets, pigs for fattening, sows in order to have benefit in piglets, ornamental fish, dogs and all avian species ([EFSA-Q-2021-00169](#))

This question refers to the authorisation under Article 4 and the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of Calsporin® (*Bacillus velezensis* DSM 15544) as a zootechnical additive for pigs, avian species, dogs and ornamental fish.

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

5.18. Nor-Balm® (*Melissa officinalis* dry extract) for all animal species ([EFSA-Q-2021-00175](#))

EFSA was requested to deliver an opinion on the safety of Nor-Balm® (*Melissa officinalis* dry extract) as a sensory additive for all animal species based on the additional information provided by the applicant.

The draft opinion was discussed focusing on the characterisation and the safety 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-2021-00497	BioStabil <i>Lactiplantibacillus</i> (previously <i>Lactobacillus</i>) <i>plantarum</i> DSM 19457 for all animal species
EFSA-Q-2021-00498	Ronozyme® Multigrain (endo-1,4-beta-xylanase (EC 3.2.1.8), endo-1,3(4)-beta-glucanase (EC 3.2.1.6) and endo-1,4-beta-glucanase (EC 3.2.1.4), produced by <i>Trichoderma reesei</i> (ATCC 74444)) for poultry for fattening other than turkeys for fattening, poultry for laying, turkeys for fattening, piglets (weaned) and pigs for fattening
EFSA-Q-2021-00501	BLIS K12 (<i>Streptococcus salivarius</i> K12) for pets and other non food-producing animals
EFSA-Q-2021-00515	Fimix (montmorillonite-illite) for dairy cows for milk production and other dairy ruminants

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

7.1. Scientific Committee/Scientific Panels

- The Chair of the Panel reported on the last plenary meeting of the Scientific Committee, in which the opinion on non-monotonic dose response (EFSA-Q-2019-00530) was adopted.
- José Tarazona gave an overview of two guidance documents recently adopted by the Scientific Committee of EFSA: Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health⁷, and Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles⁸.

7.2. EFSA

- The Head of the REPRO Department, Guilhem de Seze, explained the reasons behind EFSA's new organisational structure. In order to implement the new obligations and new processes required by the Transparency Regulation (TR), the ART Programme designed a harmonised high-level Risk Assessment (RA) process divided in four main steps: Mandate & dossier intake, Preliminary activities to Risk Assessment, Risk Assessment, and Output publication & dissemination. To best support the changes triggered by the TR, the subsequent step was to redesign EFSA's internal structure: among other changes, EFSA will have one department focusing on RA production (ASSESS Department), and one focusing on services in support of RA production (ENABLE Department). The Head of the REPRO Department also gave an overview of the most recent declarations of interest (DOI) issues, explaining that while the technical Task Force is working on the issues reported, the automatic request for expert DOI submission has been disabled from 18 September. Experts will be asked to use the alternative workflow described in the EFSA Competing Interest Management rules.

⁷ <https://www.efsa.europa.eu/en/efsajournal/pub/6768>

⁸ <https://www.efsa.europa.eu/en/efsajournal/pub/6769>



7.3. European Commission

Not discussed

8. Other scientific topics for information/or discussion

- a) The Panel discussed about the need to revise and update some of its guidance documents regarding the assessment of feed additives. The Panel agreed to request the Executive Director for the endorsement of this self-task.

9. Any other business

- a) The Panel was informed on an erratum in the opinion on “Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) for all pigs and other minor porcine species” ([EFSA-Q-2020-00600](#)) and another in the opinion on “Mandarin oil (BDG 8) for all animal species” ([EFSA-Q-2010-01517](#), [EFSA-Q-2021-00143](#)). These errata will be corrected.
- b) The next Plenary meeting (10-11 November) will have a session open to observers.
- c) The Plenary meeting scheduled for 9 December has been cancelled.