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

168th Plenary meeting 4-6 July 2023

09:00-18:00 / 09:00-18:00 / 9:00-13:00

MINUTES – agreed on 19 July 2023

Location: European Food Safety Authority (Parma)

Participants:

- **Panel Members:**

  Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen[1], Birgit Dusemund, Mojca Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente[1], Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

- **Hearing Experts:**

  Not applicable.

- **European Commission:**

  Not applicable.

- **EFSA:**

  FEEDCO Unit: Natalia Alija Novo, Angelica Amaduzzi, Arianna Angelini, Montserrat Anguita, Nicole Bozzi Cionci, Yvette Dirven, Joana Firmino, Stefani Fruk, Jaume Galobart, Yolanda García Cazorla, Mary Bridget Gilsenan, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Paola Manini, Alberto Navarro Villa, Jordi Ortuño, Daniel Pagés Plaza, Elisa Pettenati, Fabiola Pizzo, Anita Radovnikovic, Joana Revez, Barbara Rossi, Jordi Tarrés-Call and Maria Vittoria Vettori.

- **Others:**

  Not applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted after the inclusion of the items "AGal-Pro BL and AGal-Pro BL-L (alpha-galactosidase (EC3.2.1.22), endo-1,4-betaglucanase (EC3.2.1.4)) for chickens and minor poultry species for fattening and chickens reared for laying (EFSA-Q-2021-00128)", "Xygest™ HT (endo-1,4-beta-xylanase (EC 3.2.1.8)) for all pigs (EFSA-Q-2022-00323)" and "Botanically defined flavourings from Botanical Group 07 - Geraniales, Myrtales, Poales for all animal species and categories: Geranium rose oil (EFSA-Q-2023-00034)" and the removal of "Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Anise star terpenes (EFSA-Q-2023-00399)".

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to

[1] Attended via webconference
[2] Policy on Independence
[3] Competing Interest Management

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 167th FEEDAP Plenary meeting

The minutes of the 167th FEEDAP Plenary meeting were agreed by written procedure on 29 May 2023.[4]

The Panel adopted the following opinions in written procedure:

- CanBiocin k-9 Heritage Probiotic Blend for dogs (EFSA-Q-2021-00383) adopted on 26th of May 2023
- L-Valine produced by *Corynebacterium glutamicum* CGMCC 18932 for all animal species (EFSA-Q-2021-00566) adopted on 5th of June 2023

5. Scientific topics for discussion

5.1. 25-Hydroxycholecalciferol for pigs and poultry (EFSA-Q-2019-00104)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of 25-hydroxycholecalciferol as a nutritional additive for pigs and poultry.

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

5.2. AGal-Pro BL and AGal-Pro BL-L (alpha-galactosidase (EC3.2.1.22), endo-1,4-betaglucanase (EC3.2.1.4)) for chickens and minor poultry species for fattening and chickens reared for laying (EFSA-Q-2021-00128)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of AGal-Pro BL and AGal-Pro BL-L (alpha-galactosidase (EC3.2.1.22), endo-1,4-betaglucanase (EC3.2.1.4)) as a zootechnical additive for chickens for fattening, minor poultry species for fattening and chickens reared for laying.

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

5.3. Hostazym X (endo-1,4-beta-xylanase) for chickens for fattening, chickens reared for laying, minor poultry species reared for laying, laying hens, turkeys for fattening, minor poultry species for fattening, minor poultry species for laying, pigs for fattening, piglets (weaned), carp, breeding hens, turkeys for breeding, turkeys reared for breeding, minor poultry species reared for breeding, minor poultry species for breeding, ornamental birds, suckling piglets and minor pig species for fattening (EFSA-Q-2021-00153)

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 Hostazym X (endo-1,4-beta-xylanase) as a zootechnical additive for poultry species, ornamental birds, all growing pigs and carps.

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

[4] https://www.efsa.europa.eu/sites/default/files/2023-05/feedap_230511-12_m_Adopted.pdf

5.4. 25-Hydroxycholecalciferol for ruminants (EFSA-Q-2021-00341)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of 25-hydroxycholecalciferol as a nutritional additive for all ruminants.

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

5.5. VTR-xylanase (liquid) and VTR-xylanase (powder) - Endo-beta-1,4-xylanase for pigs (EFSA-Q-2021-00427) and for all avian species including ornamental, exotic and game birds (EFSA-Q-2021-00442)

These questions refer to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of VTR-xylanase as a zootechnical additive for piglets and minor growing porcine species, and for all avian species.

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

5.6. ProAct 360 (subtilisin protease produced by *Bacillus licheniformis* (DSM 33099)) for poultry species for fattening or reared for laying/breeding (EFSA-Q-2021-00544)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of ProAct 360 (subtilisin protease produced by *Bacillus licheniformis* (DSM 33099)) as a zootechnical additive for poultry species for fattening or reared for laying/breeding.

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

5.7. Kofasil Lac (*Lactiplantbacillus plantarum* DSM 3676 and *Lactiplantbacillus plantarum* DSM 3677) and Kofasil S (*Lentilactobacillus buchneri* DSM 13573) for all animal species (EFSA-Q-2021-00635)

This question refers to the renewal of the authorisations under Article 14 of Regulation (EC) No 1831/2003 of *Lactiplantibacillus plantarum* DSM 3676, *Lactiplantibacillus plantarum* DSM 3677 and *Lentilactobacillus buchneri* DSM 13573 as technological additives for all animal species.

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

5.8. Update on the Guidance on studies concerning the safety of use of the additive for users/workers (EFSA-Q-2022-00226)

This question refers to the self-task of the Panel on the update of the guidance for the assessement of the safety of feed additives for users/workers.

The draft guidance was discussed. The Panel endorsed the draft guidance for public consultation.

5.9. *Lactiplantibacillus plantarum* NCIMB 30083 (formerly *Lactobacillus plantarum* NCIMB 30083) for all animal species (EFSA-Q-2022-00317)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Lactiplantibacillus plantarum* NCIMB 30083 (formerly *Lactobacillus plantarum* NCIMB 30083) as a technological additive for all animal species.

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

5.10. *Lactiplantibacillus plantarum* NCIMB 30084 for all animal species (EFSA-Q-2022-00322)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Lactiplantibacillus plantarum* NCIMB 30084 as a technological additive for all animal species.

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

5.11. Xygest™ HT (endo-1,4-beta-xylanase (EC 3.2.1.8)) for all pigs (EFSA-Q-2022-00323)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Xygest™ HT (endo-1,4-beta-xylanase (EC 3.2.1.8)) as a zootechnical additive for all pigs.

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The Panel endorsed the draft and will be considered for written adoption after the outcome of the public consultation is addressed.

5.12. GalliPro® Fit (*Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840) for all poultry species for fattening or reared for laying or reared for breeding (EFSA-Q-2022-00325)

This question refers to the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of GalliPro® Fit (*Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840) as a zootechnical additive for all poultry species for fattening or reared for laying/breeding.

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

5.13. KemTRACE Chromium (Chromium propionate) for all growing birds (EFSA-Q-2022-00350)

This question refers to the authorisation under Article 4 and modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of KemTRACE Chromium (chromium propionate) as a zootechnical additive for all growing birds.

The draft opinion was discussed. The Panel agreed that additional information is necessary and will be requested to the applicant.

5.14. Sodium hydroxide for dogs, cats and ornamental fish (EFSA-Q-2022-00376)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of sodium hydroxide as a technological additive for dogs, cats and ornamental fish.

The draft opinion was discussed focusing on the characterisation and the safety of the additive. The Panel endorsed the draft and will be considered for written adoption after the outcome of the public consultation is addressed.

5.15. Acetic acid, calcium acetate and sodium diacetate for fish (EFSA-Q-2022-00546)

EFSA was requested to deliver an opinion on the safety of acetic acid, calcium acetate and sodium diacetate as a technological additive for fish.

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

5.16. Iron (II) - betaine complex for all animal species (EFSA-Q-2022-00624)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of iron (II) - betaine complex 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 endorsed the draft and will be considered for written adoption after the outcome of the public consultation is addressed.

5.17. *Enterococcus faecium* (ATCC 53519 and ATCC 55593) (EFSA-Q-2023-00019)

EFSA was requested to deliver an opinion on the efficacy of *Enterococcus faecium* (ATCC 53519 and ATCC 55593) as a technological additive for all animal species.

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

5.18. Botanically defined flavourings from Botanical Group 07 - Geraniales, Myrtales, Poales for all animal species and categories: Geranium rose oil (EFSA-Q-2023-00034)

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

The draft opinion was discussed in the 165th Plenary meeting. The Panel unanimously adopted the opinion.

5.19. Botanically defined flavourings from Botanical Group 07 - Geraniales, Myrtales, Poales for all animal species and categories: Eucalyptus oil (EFSA-Q-2023-00395)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of eucalyptus oil 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.

5.20. Botanically defined flavourings from Botanical Group 07 - Geraniales, Myrtales, Poales for all animal species and categories: Lemongrass oil (EFSA-Q-2023-00396)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of lemongrass oil 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.

5.21. Botanically defined flavourings from Botanical Group 07 - Geraniales, Myrtales, Poales for all animal species and categories: Clove oil (EFSA-Q-2023-00397)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of clove oil 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.

5.22. Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Anise star oil (EFSA-Q-2023-00398)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of anise star oil 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.

5.23. Botanically defined flavourings from Botanical Group 18 - Gymnosperms (Coniferales, Ginkgoales) for all animal species and categories: Pine tincture (EFSA-Q-2023-00400)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of pine tincture 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.

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-2023-00355	*Levilactobacillus brevis* 16680 for all animal species
EFSA-Q-2023-00362	*Loigolactobacillus coryniformis* DSM34345
EFSA-Q-2023-00363	*Limosilactobacillus fermentum* NCIMB 30169
EFSA-Q-2023-00391	Vermiculite for all animal species
EFSA-Q-2023-00392	*Lentilactobacillus buchneri* BioCC 228 DSM 32651
EFSA-Q-2023-00409	'Vitamin B12' or 'cyanocobalamin' produced by *Ensifer adhaerens* CGMCC 21299
EFSA-Q-2023-00436	L-Cystine from fermentation with *E. coli* K12 DSM34232
EFSA-Q-2023-00437	L-Cysteine and its hydrochlorides produced by electrochemical reduction of L-Cystine
EFSA-Q-2023-00439	L-valine produced by fermentation with *Corynebacterium glutamicum* KCCM 80365
EFSA-Q-2023-00440	Lanthanum carbonate octahydrate for use in dogs

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-2022-00513	4b1710 (*Saccharomyces c.* MUCL 39885) on Cattle for fattening	08/05/2023
EFSA-Q-2022-00554	Choline chloride (3a890)	31/05/2023
EFSA-Q-2022-00745	Coated granulated cobalt (II) carbonate 3b304	15/05/2023
EFSA-Q-2022-00791	L-Cystine 3c391	15/05/2023
EFSA-Q-2022-00799	Bentonite	14/06/2023
EFSA-Q-2022-00811	Difructose anhydride III (NITTEN DFAIII)	08/06/2023
EFSA-Q-2022-00819	*Saccharomyces cerevisiae* for piglets (suckling and weaned piglets), dairy sheep (for milk production) and lambs for fattening	01/06/2023
EFSA-Q-2022-00828	*Lactiplantibacillus plantarum* NCIMB 40027	26/05/2023
EFSA-Q-2022-00840	Natural mixture of illite-illite/smectite mixed layer	29/06/2023
EFSA-Q-2022-00876	*Enterococcus faecium* NCIMB 11181	23/05/2023
EFSA-Q-2022-00879	Ammonium propionate (1k284)	23/05/2023
EFSA-Q-2023-00249	*Lactococcus lactis* DSM 34262	26/06/2023
EFSA-Q-2023-00252	*Enterococcus faecium* DSM 22502	31/05/2023
EFSA-Q-2023-00276	*Levilactobacillus brevis* DSM 23231	06/06/2023

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-2022-00742	*Duddingtonia flagrans* (Dudd) Cooke NCIMB 30336
EFSA-Q-2022-00860	Actisaf® Sc47 (*Saccharomyces cerevisiae* NCYC SC 47) for cattle for fattening, dairy cows, piglets (weaned) and sows
EFSA-Q-2023-00352	TYFER™ Chelate (ferric tyrosine chelate) for chicken, turkeys and minor poulty species for fattening or reared for laying/breading
EFSA-Q-2023-00353	Aviax® 5% (semduramicin sodium) for chickens for fattening
EFSA-Q-2023-00376	Nutrase P (6-phytase) for chickens for fattening, other poultry for fattening, reared for laying and ornamental birds
EFSA-Q-2023-00401	Copper (II) - betaine complex for all animal species

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

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

7.1. Scientific Committee/Scientific Panels

The Chair of the Panel provided a short update on the last plenary of the Scientific Committee, held on 28-29 June 2023.

7.2. EFSA

Not discussed.

7.3. European Commission/EURL

The European Union Reference Laboratory (EURL) has recently finished an addendum of the EURL evaluation report for Urea linked to FAD-2010-0113. The Regulation (EC) No

2003/2003 included in the authorising Regulation had been repealed, and the analytical methods need to be updated with the EN standards now available for: i) the determination of the total nitrogen in the additive: Titrimetry (EN 15478) and ii) the determination of the biuret contribution to the total nitrogen in the additive: Spectrophotometry (EN 15479).

8. Other scientific topics for information and/or discussion

8.1. EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms and EFSA statement on the requirement for whole genome sequence analysis of microorganisms intentionally used in the food chain

The Panel was informed on the ongoing work on the update of the document. The update will consider the new data/technologies/tools that have become available since their adoption and the experience gained during their implementation. The timeline for the update was presented.

8.2. Microorganisms Pipelines Service - MoPS

The Panel was informed on the Microorganisms Pipelines Service (MoPS) project. The project aims to develop and implement a tool to support risk assessors in the characterisation and evaluation of microorganisms. The timeline of the project was presented.

8.3. Feedback on the meetings with stakeholders regarding the assessment of microorganisms and the update of the guidance on efficacy

The Panel was informed on the meetings held with stakeholders on 20 and 28 June to discuss the ongoing work on the revision of the requirements for the assessment of microorganisms used as feed additives or productions strains and on the update of the guidance on efficacy, respectively.

8.4. Self-task of the FEEDAP and CONTAM Panels on a revised animal dietary exposure assessment model

The Executive Director of EFSA accepted the self-task of the FEEDAP and CONTAM Panels to produce a revised animal exposure assessment model (EFSA-Q-2023-00406). The aim is to align to the current dietary recommendations/practices the model diets and requirements of the target animals used in some opinions of the CONTAM Panel[5]. A Scientific Statement is expected to be completed by the end of March 2024.

9. Any other business

a) Maria de Lourdes Bastos has been appointed Chair of the newly created Working Group on Characterisation of feed additives.
b) Yolanda Sanz informed the Panel of her intention to resign as a member of the Panel and its working groups.

[5] https://www.efsa.europa.eu/sites/default/files/2023-04/feedap_230321-23_m.pdf