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

172nd Plenary Meeting



08:30-16:00 / 08:30-16:00 / 08:30-11:30

MINUTES - Agreed on 22 March 2024



Location: Thessaloniki (Greece)

Attendees:

o Panel Members:

Giovanna Azimonti, Vasileios Bampidis (Chair), Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca 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 Experts¹:

Not applicable.

o European Commission and/or Member States representatives:

Not applicable.

o EFSA:

FEEDCO Unit: Angelica Amaduzzi, Montserrat Anguita, Nicole Bozzi Cionci, Rosella Brozzi, Anna Dioni, Maria Dulak-Lis, Joana P. Firmino, 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, Piera Valeri and Maria Vittoria Vettori.

Executive Director: Bernhard Url²

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 "Plexomin® Se 3000/Plexomin® Se 3000 micro (Selenised yeast *Saccharomyces cerevisiae* Y03-0 inactivated) for all animal species ($\underline{\mathsf{EFSA-Q-2021-00309}}$)" and "TYFERTM Chelate (ferric tyrosine chelate) for chickens, turkeys and minor poultry species for fattening or reared for laying/breeding ($\underline{\mathsf{EFSA-Q-2023-00352}}$)".

3. Declarations of interest of Panel members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of

Competing Interest Management

As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

Attended on 12 March 2024 for item 9.3.a

Policy on Independence



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. Agreement of the minutes of the 171st FEEDAP Panel plenary meeting held on 30 January – 1 February 2024 via teleconference

The minutes of the 171st FEEDAP Plenary meeting were agreed by written procedure on 16 February 2024.⁵

5. Report on written procedures

The Panel adopted the following opinions by written procedure since the last plenary meeting:

 PB6 Bacillus velezensis ATCC PTA-6737 for all growing poultry (<u>EFSA-Q-2022-00746</u>) adopted on 2 February 2024

6. Scientific outputs submitted for discussion/adoption

6.1 Plexomin® Se 3000/Plexomin® Se 3000 micro (Selenised yeast *Saccharomyces cerevisiae* Y03-0 inactivated) for all animal species (<u>EFSA-Q-2021-00309</u>)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Plexomin[®] Se 3000/Plexomin[®] Se 3000 micro (Selenised yeast *Saccharomyces cerevisiae* Y03-0 inactivated) as a nutritional additive for all animal species.

The draft opinion was adopted in the 171st Plenary meeting of the FEEDAP Panel. However, after adoption, it was identified that some data was inadequately included in the assessment of the safety for the environment. Therefore, the Panel agreed to withdraw the adoption of the opinion. An updated draft opinion considering the relevant information was discussed; the discussion focused on the safety of the additive for the environment. The Panel unanimously adopted the opinion.

6.2 Quantum Blue 6-phytase for fish (EFSA-0-2021-00313)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Quantum Blue (6-phytase) as a zootechnical additive for fish.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

6.3 Patent Blue V for all non-food producing species (<u>EFSA-Q-2022-00478</u>)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Patent Blue V as a sensory additive for all non-food producing species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and safety. The Panel unanimously adopted the opinion.

6.4 BIOSPRINT® (4b-1710 Saccharomyces cerevisiae MUCL 39885) for cattle for fattening (EFSA-Q-2022-00513)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of BIOSPRINT® (4b-1710 *Saccharomyces cerevisiae* MUCL 39885) as a zootechnical additive for cattle for fattening.

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https://www.efsa.europa.eu/sites/default/files/2024-02/feedap_240130-0201_m.pdf



The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and safety. The Panel unanimously adopted the opinion.

6.5 Levilactobacillus brevis (formerly Lactobacillus brevis) DSMZ 21982 for all animal species (EFSA-0-2022-00581)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Levilactobacillus brevis* (formerly *Lactobacillus brevis*) DSMZ 21982 as a technological additive for all animal species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and safety. The Panel unanimously adopted the opinion.

6.6 Actisaf® Sc47 (Saccharomyces cerevisiae CNCM I-4407) for cattle for fattening (EFSA-0-2022-00860)

EFSA was requested to deliver an opinion on the efficacy of Actisaf® Sc47 (*Saccharomyces cerevisiae* CNCM I-4407) as a zootechnical additive for cattle for fattening.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product efficacy. The Panel unanimously adopted the opinion.

6.7 L-Tryptophan for all animal species (EFSA-0-2023-00048)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-tryptophan as a nutritional additive for all animal species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

6.8 L-Threonine for all animal species (EFSA-Q-2023-00049)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-threonine as a nutritional additive for all animal species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

6.9 Pediococcus pentosaceus DSM 14021 for all animal species (EFSA-Q-2023-00164)

This question refers to renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Pediococcus pentosaceus* DSM 14021 as a technological additive for all animal species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and safety. The Panel unanimously adopted the opinion.

6.10 L-Isoleucine for all animal species (EFSA-Q-2023-00207)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-isoleucine as a nutritional additive for all animal species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

6.11 TYFER™ Chelate (ferric tyrosine chelate) for chickens, turkeys and minor poultry species for fattening or reared for laying/breeding (EFSA-Q-2023-00352)

EFSA was requested to deliver an opinion on the safety of TYFER $^{\text{\tiny M}}$ Chelate (ferric tyrosine chelate) as a zootechnical additive for chickens, turkeys and minor poultry species for fattening or reared for laying/breeding.



The Panel discussed the draft scientific opinion, and in particular assessed data regarding the product characterisation and safety for the user. The Panel unanimously adopted the opinion.

6.12 Vitamin B12 or cyanocobalamin produced by *Ensifer adhaerens* CGMCC 21299 for all animal species (<u>EFSA-Q-2023-00409</u>)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of vitamin B12 or cyanocobalamin produced by *Ensifer adhaerens* CGMCC 21299 as a nutritional additive for all animal species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel endorsed the opinion which will be considered for written adoption after the outcome of the public consultation is addressed.

6.13 Lanthanum carbonate octahydrate for pets and other non food-producing animals (EFSA-Q-2023-00440)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of lanthanum carbonate octahydrate as a zootechnical additive for pets and other non food-producing animals.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

6.14 4-Hydroxy-2,5-dimethylfuran-3(2H)-one (2b13010) for cats and dogs (<u>EFSA-Q-2023-00688</u>)

This question refers to the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of 4-hydroxy-2,5-dimethylfuran-3(2H)-one (2b13010) as a sensory additive for cats and dogs.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and safety. The Panel unanimously adopted the opinion.

6.15 BioCell® (Saccharomyces cerevisiae DBVPG 48 SF) for horses, pigs and ruminants (EFSA-Q-2023-00694)

EFSA was requested to deliver an opinion on the efficacy of BioCell® (*Saccharomyces cerevisiae* DBVPG 48 SF) as a zootechnical additive for horses, pigs and ruminants.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product efficacy. The Panel unanimously adopted the opinion.

6.16 Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Ginseng tincture (EFSA-Q-2024-00055)

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

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

6.17 Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Omicha tincture (EFSA-Q-2024-00061)

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



The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

6.18 Botanically defined flavourings from Botanical Group 18 - Gymnosperms (Coniferales, Ginkgoales) for all animal species and categories: Ginkgo extract (EFSA-O-2024-00063)

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

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

6.19 Botanically defined flavourings from Botanical Group 07 - Geraniales, Myrtales, Poales for all animal species and categories: *Melaleuca cajuputi* oil (EFSA-Q-2024-00118)

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

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

6.20 Botanically defined flavourings from Botanical Group 07 - Geraniales, Myrtales, Poales for all animal species and categories: Tea tree oil (EFSA-Q-2024-00119)

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

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel identified some aspects that required further revision and asked the Working Group to present an updated draft in a future plenary meeting.

7. Other scientific topics for information/discussion

7.1 Renewal of authorisation for coccidiostats

The FEEDAP Panel discussed on the requirements for the renewal of the authorisations of coccidiostats and histomonostats. The Panel considers that for applications for the renewal of these category of additives, tolerance studies in the relevant target species are required. These tolerance studies should be performed according to the most updated guidance document at time of submission of the application for renewal of the authorisation and should not be older than three years at the time of submission.

Applicants should use these tolerance studies to collect samples of tissues and products for residue determination, following the most up to date analytical methods, for an updated assessment of consumer exposure.

7.2 Statement on how to interpret the QPS qualification on 'acquired antimicrobial resistance genes'

The FEEDAP Panel was informed on the BIOHAZ Panel's "Statement on how to interpret the QPS qualification on 'acquired antimicrobial resistance genes"⁶, which defines the terms 'intrinsic' and 'acquired' Antimicrobial Resistance (AMR) genes for the purpose of EFSA's risk assessment and provides guidance on how to demonstrate the 'intrinsic'/'acquired' nature of

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⁶ https://www.efsa.europa.eu/en/efsajournal/pub/8323



an AMR gene following a bioinformatic approach. The Panel acknowledges the statement which is considered to apply to the assessment of feed additives. Therefore, applicants are advised to consider it in the preparation of their applications for feed additives.

7.3 Assessment of feed additives consisting of or containing nanoparticles

A brief discussion took place on the characterisation of feed additives to determine the presence of small particles including nanoparticles. Due to lack of time, the discussion will continue in the next plenary.

8. Update on new mandates since the previous meeting

8.1 New applications under Regulation (EC) 1831/2003

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-2024-00081	$\ensuremath{RONOZYME}^{\ensuremath{@}}$ RumiStar (alpha-amylase 3.2.1.1) for dairy cows for milk production
EFSA-Q-2024-00090	FlorEquilibre Chat (Preparation of Lactobacillus acidophilus CNCM I-3231, Ligilactobacillus salivarius CNCM I-3233, Lacticaseibacillus paracasei CNCM I-4901, Bifidobacterium longum CNCM I-3227, Bifidobacterium animalis subsp. lactis CNCM I-3993) for cats
EFSA-Q-2024-00091	L-Isoleucine (min.90%, min.65%) produced by <i>Corynebacterium glutamicum</i> KCCM80388 for all animal species
EFSA-Q-2024-00121	L-Valine for all animal species
EFSA-Q-2024-00123	XTRACT RUMINANT, CODE X60-7065 (Preparation of eugenol, cinnamaldehyde and capsicum oleoresin) for dairy cows for milk production and cows for reproduction

8.2 Valid applications under Regulation (EC) No 1831/2003

Applications considered valid for the start of the assessment:

EFSA-Q number	Subject	Valid on
EFSA-Q-2022-00356	Rhodimet® NP99, MetAMINO®, Sandimet®, Sumimet®-P (DL-methionine, technically pure, 3c301); Smartamine® M, Kessent® M (DL-methionine protected with copolymer vinylpyridine/styrene, 3c303); Mepron® (DL-methionine protected with ethylcellulose, 3c304); Rhodimet® AT88, Alimet®, Sumimet®-L (Hydroxy analogue of methionine, 3c307); MHA® (Calcium salt of hydroxy analogue of methionine, 3c308); MetaSmart® L, Kessent® MF (Isopropyl ester of hydroxy analogue of methionine, 3c309); 3c301, 3c307 and 3c308 for all animal species, 3c303, 3c304 and 3c309 for ruminants	19/02/2024
EFSA-Q-2023-00262	CAPSOZYME SB PLUS (endo-1,4-beta-xylanase and alpha-galactosidase) for turkeys	02/02/2024
EFSA-Q-2023-00325	Enterosure Conc (Bacillus velezensis ATCC PTA-6737, Bacillus velezensis ATCC PTA-127114, Bacillus licheniformis ATCC-127113) for all growing avian species	27/02/2024



EFSA-Q number	Subject	Valid on
EFSA-Q-2023-00705	Inositol (3a900) for fish and crustaceans	23/01/2024
EFSA-Q-2023-00712	L-Lysine sulphate produced by <i>Corynebacterium</i> glutamicum for all animal species	19/02/2024
EFSA-Q-2023-00722	4-Hydroxy-2,5-dimethylfuran-3(2H)-one for all animal species with the exception of cats and dogs	05/03/2024
EFSA-Q-2023-00723	L-Lysine monohydrochloride for all animal species	29/01/2024
EFSA-Q-2023-00724	Saccharomyces cerevisiae CNCM I-1077 for lambs, all minor ruminant species for fattening, camelids for fattening, ruminants reared for milk production/suckling/reproduction, camelids reared for milk production/suckling/reproduction, equidae other than horses	29/02/2024
EFSA-Q-2023-00739	L-Valine for all animal species	16/02/2024
EFSA-Q-2023-00748	Interban $^{\mbox{\scriptsize \$}}$ (10 % Narasin and 0.2 % Diclazuril) for poultry	05/02/2024
EFSA-Q-2023-00865	L-Lysine sulphate produced by <i>Corynebacterium</i> glutamicum for all animal species	06/03/2024
EFSA-Q-2023-00866	L-Tryptophan (min.98%) produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM80346 for all animal species	27/02/2024
EFSA-Q-2023-00868	L-Arginine produced by E. coli for all animal species	26/02/2024
EFSA-Q-2023-00901	Copper Bilysinate for all animal species	05/03/2024

8.3 New questions under Regulation (EC) No 178/2002

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EFSA-Q number	Subject
EFSA-Q-2023-00738	3-phytase produced by <i>Komagataella phaffii</i> (CECT 13171) presented in solid (FSF10000) and liquid (FLF1000) forms for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, minor poultry species, pigs for fattening and minor porcine species for fattening
EFSA-Q-2024-00023	Ferric (III) ammonium hexacyanoferrate (II) (AFCF) for ruminants (domestic and wild), calves prior to the start of rumination, sheep, lambs prior to the start of rumination, goats, kids prior to the start of rumination and pigs (domestic and wild)
EFSA-Q-2024-00051	Enterococcus faecium (ATCC 53519 and ATCC 55593) as silage additives for all animal species
EFSA-Q-2024-00053	Potassium hexacyanoferrat (II)(potassium ferrocyanide) and Natriumhexacyanoferrat(II)-ferrocyannatrium (sodium ferrocyanide) for all animal species
EFSA-Q-2024-00056	Vitamin B12/Cyanocobalamin produced by fermentation with non- genetically modified <i>Ensifer adhaerens</i> CGMCC 19596 for all animal species

9. Feedback from Scientific Committee/Scientific Panels/EFSA/European Commission/EURL

9.1 Scientific Committee

The Chair of the Panel provided an overview of the last plenary meeting of the Scientific Committee.



9.2 Scientific Panel(s) including their Working Groups

Not discussed.

9.3 EFSA

- a) The Executive Director of EFSA thanked the FEEDAP Panel for the work and the achievements of the last six years.
- b) The Panel was informed on the outcome of the public consultation on the guidance for the assessment of the efficacy of feed additives. The relevant comments received will be assessed and considered in the final draft guidance for adoption by the Panel.

9.4 European Commission/EURL

Not discussed.

10. Any other business

10.1 Appreciation of former FEEDAP Panel members

The Panel acknowledged the continued contributions by several former FEEDAP Panel members who are still actively involved in the current Working Groups of the Panel.

10.2 Next meeting

The next meeting will be held on 17-18 April 2024 via teleconference. The Panel was also informed that the plenary meeting of 4-6 June 2024 will be open to observers.