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



171st Plenary meeting 30 January – 1 February 2024 09:00-18:00 / 09:00-18:00 / 09:00-13:00 **MINUTES** – agreed on 16 February 2024

Location: Online Participants:

• 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 Experts:

Not applicable.

• European Commission:

Paola Ferraro, Francesca Moretti, Almudena Rodríguez – DG SANTE¹

EFSA:

FEEDCO Unit: Angelica Amaduzzi, Montserrat Anguita, Nicole Bozzi Cionci, Rosella Brozzi, Anna Dioni, Maria Dulak, Joana 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.

Others:

Not applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants. The Chair welcomed Maria Dulak as a new member of the FEEDCO Unit.

2. Adoption of agenda

The agenda was adopted without modifications.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, 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.

Present on 31 January for item 8.1

² Policy on Independence

Competing Interest Management



4. Report on written procedures since the 170th FEEDAP Plenary meeting

The minutes of the 170th FEEDAP Plenary meeting were agreed by written procedure on 4 December 2023.⁴

The Panel adopted the following opinions by written procedure:

- Lentilactobacillus buchneri NCIMB 30139 1k20734 for all animal species (<u>EFSA-Q-2022-00198</u>) adopted on 6 December 2023
- Lentilactobacillus buchneri (formerly Lactobacillus buchneri) DSM 22501 for all animal species (EFSA-Q-2022-00789) adopted on 11 December 2023
- PB6 (*Bacillus vezelezensis* ATCC PTA-6737) for pigs (<u>EFSA-Q-2022-00320</u>) adopted on 5 January 2024
- 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). The Panel withdrew the adoption of the opinion of 5 July 2023, and adopted an updated opinion on 12 January 2024

5. Scientific topics for discussion

5.1. Coxidin (monensin sodium) for chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (<u>EFSA-Q-2016-00643</u>, <u>EFSA-Q-2020-00405</u>, <u>EFSA-Q-2020-00837</u>, <u>EFSA-Q-2021-00074</u>)

These questions refer to the renewal of the authorisations under Article 14 and the authorisation of new uses under Article 4 of Regulation (EC) No 1831/2003 of Coxidin (monensin sodium) as a coccidiostat for chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding.

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

5.2. Monteban® G100 (narasin) for chickens for fattening (<u>EFSA-Q-2020-00557</u>)

EFSA was requested to deliver an opinion on the safety and efficacy of Monteban® G100 (narasin) as a coccidiostat for chickens for fattening.

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

5.3. Plexomin® Se 3000/Plexomin® Se 3000 micro (Selenised yeast Saccharomyces cerevisiae Y03-0 inactivated) for all animal species (EFSA-Q-2021-00309)

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.

^{4 &}lt;a href="https://www.efsa.europa.eu/sites/default/files/2023-12/feedap-231114-16-m.pdf">https://www.efsa.europa.eu/sites/default/files/2023-12/feedap-231114-16-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. Quantum Blue 6-phytase for fish (EFSA-Q-2021-00313)

Not discussed due to lack of time.

5.5. Free Yeast® F (fumonisin B1 esterase (3.1.1.87) produced by Komagataella phaffii NCAIM (P) Y001485) for piglets (suckling and weaned), pigs for fattening, sows for reproduction and sows in order to have benefit in piglets (EFSA-Q-2021-00470)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of fumonisin B1 esterase produced by *Komagataella phaffii* NCAIM (P) Y001485 as a technological additive for piglets (suckling and weaned), pigs for fattening, sows for reproduction and sows in order to have benefit in piglets.

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

5.6. Microcrystalline cellulose and carboxymethyl cellulose for all animal species (<u>EFSA-Q-2021-00582</u>)

EFSA was requested to deliver an opinion on the safety of microcrystalline cellulose and carboxymethyl cellulose as technological additives for all animal species.

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

5.7. Hydroxypropyl cellulose E 463 for all animal species (<u>EFSA-Q-2021-00585</u>)

EFSA was requested to deliver an opinion on the safety of hydroxypropyl cellulose E 463 as a technological additive for all animal species.

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

5.8. Ethyl cellulose E 462 for all animal species (EFSA-Q-2021-00734)

EFSA was requested to deliver an opinion on the safety of ethyl cellulose E 462 as a technological additive for all animal species.

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

5.9. HiPhorius™ (6-phytase (EC 3.1.3.2.6)) for all *Suidae*, all poultry species and all fin-fish (<u>EFSA-Q-2022-00082</u>)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of HiPhoriusTM (6-phytase (EC 3.1.3.2.6)) as a zootechnical additive for all *Suidae*, all poultry and all fin fish.

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



5.10. Huvezym neXo (multi-enzyme product with endo 1,4 betaxylanase, endo 1,4 betaglucanase and xyloglucan-specific-endo-beta-1,4-glucanase activities) for all Suidae (EFSA-Q-2022-00326)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Huvezym neXo as a zootechnical additive for all *Suidae*.

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

5.11. Sodium bisulphate for food-producing animals, pets, other non-food animals (<u>EFSA-Q-2022-00402</u>)

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 sodium bisulphate as a technological additive for food-producing animals, pets and other non-food animals.

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

5.12. Hydroxypropyl methyl cellulose E 464 and Methyl cellulose E 461 for all animal species (<u>EFSA-O-2022-00439</u>)

EFSA was requested to deliver an opinion on the safety of hydroxypropyl methyl cellulose and methyl cellulose as technological additives for all animal species.

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

5.13. Nonanoic acid for all poultry species and all porcine species (<u>EFSA-Q-2022-00547</u>)

This question refers to the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of nonanoic acid as a sensory additive for all poultry and all porcine species.

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

5.14. Cylactin (*Enterococcus lactis* NCIMB 10415) for cats and dogs (<u>EFSA-Q-2022-00817</u>)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Cylactin (*Enterococcus lactis* NCIMB 10415) as a zootechnical additive for cats and dogs.

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

5.15. Enterococcus faecium NCIMB 11181 for all growing poultry, and ornamental birds (EFSA-Q-2022-00876)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Enterococcus faecium* NCIMB 11181 as a zootechnical additive for chickens for fattening and reared for laying, other poultry for fattening and reared for laying, and ornamental birds.

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



5.16. *Pediococcus pentosaceus* DSM 23689 for all animal species (<u>EFSA-Q-2023-00162</u>)

This question refers to renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Pediococcus pentosaceus* DSM 23689 as a technological additive for all animal species.

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

5.17. Pediococcus pentosaceus DSM 23688 for all animal species (<u>EFSA-Q-2023-00163</u>)

This question refers to renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Pediococcus pentosaceus* DSM 23688 as a technological additive for all animal species.

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

5.18. Nimicoat (carvacrol) for piglets (weaned) (EFSA-Q-2023-00165)

EFSA was requested to deliver an opinion on the efficacy of Nimicoat (carvacrol) as a zootechnical additive for piglets (weaned).

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

5.19. Propyl gallate for all animal species (EFSA-Q-2023-00231)

EFSA was requested to deliver an opinion on the safety of propyl gallate as a technological additive for all animal species.

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

5.20. Enterococcus faecium DSM 22502 for all animal species (EFSA-Q-2023-00252)

This question refers to renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Enterococcus faecium* DSM 22502 as a technological additive for all animal species.

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

5.21. Endo-1,4-ß-D-mannanase (Natupulse® TS/TS L) for all growing poultry species (chickens for fattening, turkeys for fattening and minor growing poultry species) and other poultry for fattening (e.g. ducks, geese, pheasants, quail, guinea fowl, ostrich) and ornamental birds (EFSA-Q-2023-00545)

EFSA was requested to deliver an opinion on the safety of Natupulse[®] TS/TS L as a zootechnical additive for all growing poultry species and other poultry for fattening and ornamental birds.

The draft opinion was discussed focusing on 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-2023-00739	L-valine for all animal species
EFSA-Q-2023-00744	1-Methoxy-4-(prop-1(trans)-enyl)benzene and Eugenol for all avian species
EFSA-Q-2023-00748	Interban® (10 % narasin and 0.2 % diclazuril) for poultry
EFSA-Q-2023-00857	Bonvital (Enterococcus lactis DSM 7134) for sows
EFSA-Q-2023-00865	L-lysine sulphate produced by <i>Corynebacterium glutamicum</i> for all animal species
EFSA-Q-2023-00866	L-tryptophan (min.98%) produced by fermentation with Corynebacterium glutamicum KCCM80346 for all animal species
EFSA-Q-2023-00867	GalliPro® Fit 10 (Bacillus subtilis DSM32324, Bacillus subtilis DSM32325 and Bacillus amyloliquefaciens DSM25840) for all poultry species for laying and for breeding
EFSA-Q-2023-00868	L-arginine produced by <i>E. coli</i> for all animal species
EFSA-Q-2023-00887	ROVABIO® PHYPLUS 5000L and ROVABIO® PHYPLUS 20000 T (6-phytase, EC 3.1.3.26) for piglets, pigs for fattening, chickens for fattening and reared for laying, turkeys for fattening and reared for breeding, other-and-minor growing poultry species and reared for laying/breeding and other-and-minor growing porcine
EFSA-Q-2023-00898	Riboflavin (Vitamin B2) and Riboflavin (Vitamin B2) (80% feed grade) produced by <i>Bacillus subtilis</i> VBB18049 for all animal species
EFSA-Q-2023-00899	ROVABIO® PHYPLUS 5000L and ROVABIO® PHYPLUS 20000 T (6-phytase, EC 3.1.3.26) for piglets, pigs for fattening, chickens for fattening and reared for laying, turkeys for fattening and reared for breeding, other-and-minor growing poultry species and reared for laying/breeding and other-and-minor growing porcine
EFSA-Q-2023-00900	Preparation containing Scansmoke PET SEF 7525 (smoke flavouring extract 2b0001) for cats and dogs
EFSA-Q-2023-00901	Copper Bilysinate for all animal species
EFSA-Q-2024-00001	Plexomin L-Cu (Copper lysinate sulfate) for all animal species
EFSA-Q-2024-00004	Avi-Carb (semduramicin 3% and nicarbazin 8%) for chickens for fattening
EFSA-Q-2024-00005	L-arginine from <i>Corynebacterium glutamicum</i> KCCM80387 for all animal species
EFSA-Q-2024-00006	Citric acid (anhydrous, monohydrate) for all animal species
EFSA-Q-2024-00007	MoNa (Molybdenum compound) for pollinator insects
EFSA-Q-2024-00008	Ecobiol®, Ecobiol® 500, Ecobiol® Plus (<i>Bacillus velezensis</i> CECT 5940) for laying hens and other bird species kept for egg production purposes
EFSA-Q-2024-00031	L-histidine and L-histidine monohydrochloride monohydrate from Corynebacterium glutamicum KCCM80389 for all animal species



EFSA-Q number	Subject						
EFSA-Q-2024-00032	L-valine (min.98%) from <i>Corynebacterium glutamicum</i> KCCM80365 for all animal species						
EFSA-Q-2024-00033	L-isoleucine for all animal species						
EFSA-Q-2024-00035	B-Act® (Bacillus licheniformis DSM 28710) for pigs						

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-2022-00846	Vitamin B_2 /Riboflavin produced by Saccharomyces cerevisiae CEN.PK113-7D for all animal species	24/11/2023
EFSA-Q-2023-00439	L-valine produced by fermentation with Corynebacterium glutamicum KCCM80365 for all animal species	22/11/2023
EFSA-Q-2023-00452	Calcium D-pantothenate for all animal species	13/11/2023
EFSA-Q-2023-00482	L-lysine base, liquid for all animal species	01/12/2023
EFSA-Q-2023-00484	L-lysine sulphate containing non-viable biomass of genetically modified <i>Corynebacterium glutamicum</i> for all animal species	27/11/2023
EFSA-Q-2023-00485	CAROPHYLL Red $^{\scriptsize (B)}$ (Canthaxanthin, 4d161g) for breeder hens	23/11/2023
EFSA-Q-2023-00543	Lactiplantibacillus plantarum DSM 16627 for all animal species	20/11/2023
EFSA-Q-2023-00548	Pediococcus acidilactici NCIMB 30005 for all animal species	12/12/2023
EFSA-Q-2023-00551	L-valine produced by fermentation with genetically modified <i>Corynebacterium glutamicum</i> KCCM 80058 for all animal species	24/11/2023
EFSA-Q-2023-00631	Bacillus subtilis DSM 33862 and Lentilactobacillus buchneri DSM 12856 for all animal species	12/12/2023
EFSA-Q-2023-00667	TechnoCare® 50 (Bacillus licheniformis DSM 33806 and Weizmannia faecalis DSM 32016) for piglets (suckling and weaned), pigs for fattening, sows and physiologically related minor growing and reproductive porcine species	17/01/2024
EFSA-Q-2023-00688	4-Hydroxy-2,5-dimethylfuran-3(2H)-one (2b13010) for cats and dogs	05/12/2023
EFSA-Q-2023-00705	Inositol (3a900) for fish and crustaceans	23/01/2024

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

EFSA-Q number	Subject				
EFSA-Q-2023-00693		(riboflavin 19833) for al	•	,	ashbyi



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

7.1. Scientific Committee/Scientific Panels

The Panel was informed on the new mandate presented to the Scientific Committee in relation to the risk assessment of microorganisms that are used in the food chain for different purposes. The assessments are linked to requests for authorisation of the products under the applicable Regulations; the products evaluated may contain the microorganism, be prepared from, or obtained with the microorganism, and the microorganisms can be genetically modified or not. EFSA considers it necessary to have one scientific guidance document detailing the requirements for the risk assessment of microorganisms that could be applied across sectors. As the Scientific Committee plays a major role in harmonising practices across areas, it was proposed that the Scientific Committee prepares a guidance document on the risk assessment of microorganisms used in the food chain to be applied across sectors. The Scientific Committee agreed on the proposal and a self-task will be prepared. At this regard, it is intended that the WG on Microbiology from the FEEDAP Panel with experts from other Panels will prepare the draft guidance for the consideration of the relevant EFSA Panels and finally for the endorsement and adoption by the Scientific Committee.

7.2. **EFSA**

- a) The Panel was updated on the meeting that took place between the FEEDCO Unit and Unit G05 of DG SANTE.
- b) The public consultation of the draft updated Guidance on the assessment of the efficacy of feed additives will close on 9 February 2024.
- c) The Panel was also updated on some changes with regards the typesetting of the opinions.
- d) EFSA has been requested to deliver an opinion on whether the additives containing selenium currently authorised still comply with the requirements of the authorisation with regards to the safety for the consumer (EFSA-Q-2023-00896). The deadline for the delivery of the opinion is 1 September 2024.

7.3. European Commission/EURL

The European Union Reference Laboratory (EURL) has recently finished an addendum of the EURL evaluation report for:

- Tribasic copper chloride linked to FAD-2010-0046 (EFSA-Q-2010-01047). The
 addendum referred to the determination of total copper in the feed additive,
 premixtures and compound feed. The EURL recommended for official control the ringtrial validated EN ISO 6869 method based on atomic absorption spectrometry (AAS)
 for the determination of total copper in the feed additive, premixtures and compound
 feed, and the ring-trial validated EN 17053 method based on inductively coupled
 plasma-mass spectrometry (ICP-MS) for the determination of total copper in
 premixtures and compound feed.
- Tetra basic zinc chloride linked to FAD-2011-0007 (EFSA-Q-2011-00124). The
 addendum referred to the determination of total zinc in the feed additive, premixtures
 and compound feed. The EURL recommended for official control the ring-trial validated
 EN ISO 6869 method based on atomic absorption spectrometry (AAS) for the
 determination of total zinc in the feed additive, premixtures and compound feed, and
 the ring-trial validated EN 17053 method based on inductively coupled plasma-mass
 spectrometry (ICP-MS) for the determination of total zinc in premixtures and compound
 feed.



Benzoic acid linked to FAD-2004-0006 (EFSA-Q-2005-007), FAD-2006-0012 (EFSA-Q-2006-0056) and FAD-2010-0029 (EFSA-Q-2010-00881). The EURL recommended for official control the ring-trial validated EN 17298 method based on liquid chromatography method with ultraviolet detection (HPLC-UV) for the determination of benzoic acid in the feed additive, premixtures and compound feed.

The Panel acknowledged this information.

8. Other scientific topics for information and/or discussion

8.1. Assessment of feed additives consisting of or containing nanoparticles

The FEEDAP Panel discussed experience gained to date on the implementation of the Scientific Committee Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health⁵ and of the Scientific Committee Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles⁶ for the safety assessments of feed additives.

The FEEDAP Panel agreed to continue characterising feed additives to determine the presence of small particles, including nano particles, based on the Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles.

In order to assess potential risks associated with the presence of nanoparticles, the Panel agreed that there is a need for practical guidance tailored to feed additive safety assessments which considers safety for the target species, users, consumers and the environment, to complement the principles described in the above guidance documents on risk assessment of nanomaterials to be applied in the food and feed chain.

Until such detailed guidance is available, the FEEDAP Panel agreed that, for any ongoing or new mandates, the risk assessment of feed additives will follow the currently available sectorial guidance documents. The Panel will update this approach when practical guidance on the risk assessment of nanomaterials relating to feed additives is available.

9. Any other business

The Panel was informed that next plenary meeting (12-14 March) will take place in Thessaloniki (Greece).

⁵ https://www.efsa.europa.eu/en/efsajournal/pub/6768

⁶ https://www.efsa.europa.eu/en/efsajournal/pub/6769