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

175th Plenary Meeting

26-27 June 2024

09:00-13:00 / 09:00-13:00

MINUTES – Agreed on 27 June 2024

Location: Teleconference

Attendees:

- **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 and/or Member States representatives:**

  Not applicable.

- **EFSA:**

  FEEDCO Unit: Angelica Amaduzzi, Montserrat Anguita, Nicole Bozzi Cionci, Rosella Brozzi, Anna Dioni, Joana P. Firmino, Jaume Galobart, Yolanda García-Cazorla, Mary Bridget Gilsenan, Orsolya Holczknecht, Laura Iancu, Matteo Lorenzo Innocenti, Paola Manini, Alberto Navarro-Villa, Jordi Ortuño, Daniel Pagés Plaza, Fabiola Pizzo, Anita Radovnikovic, Joana Revez, Jordi Tarrés-Call, Piera Valeri 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 item "Propyl gallate for all animal species (EFSA-Q-2023-00231)".

3. Declarations of interest of Panel members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

1 Policy on Independence
2 Competing Interest Management

4. Agreement of the minutes of the 174th FEEDAP Panel plenary meeting held on 4-6 June 2024 in Parma

The minutes of the 174th FEEDAP Plenary meeting were agreed.[3]

5. Report on written procedures

No written procedures to report.

6. Scientific outputs submitted for discussion/adoption

6.1 Indigo carmine for cats, dogs and ornamental fish (EFSA-Q-2017-00502)

EFSA was requested to deliver an opinion on the safety of indigo carmine as a sensory additive for cats, dogs and ornamental fish.

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

6.2 Red carotenoid rich *Paracoccus carotinifaciens* (Panaferd-AX) for salmon and trout (EFSA-Q-2017-00694)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of red carotenoid rich *Paracoccus carotinifaciens* NITE SD 00017 as a sensory additive for salmon and trout.
The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and safety. The Panel unanimously adopted the opinion.

6.3 Clinacox 0.5% (diclazuril) for chickens for fattening and chickens reared for laying (EFSA-Q-2020-00201, EFSA-Q-2020-00203)

These questions refer to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Clinacox 0.5% (diclazuril) as a coccidiostat for chickens for fattening and chickens reared for laying.

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 Actisaf Sc47 (*Saccharomyces cerevisiae* CNCM I-4407) for rabbits for fattening and other non-food producing rabbits (EFSA-Q-2021-00382)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Actisaf Sc47 (*Saccharomyces cerevisiae* CNCM I-4407) as a zootechnical additive for rabbits for fattening and other non-food producing rabbits.

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 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 scientific opinion was initially adopted on 31 January 2024. However, after adoption, it was identified that the opinion did not clearly conclude on the safety for all animal species. Therefore, the Panel agreed to withdraw the adoption of the opinion. An updated

[3] https://www.efsa.europa.eu/sites/default/files/2024-07/-minutes.pdf

draft opinion addressing the missing aspect was discussed; the discussion focused on the safety of the additive for the target species. The Panel unanimously adopted the opinion.

6.6 *Lactococcus lactis* DSM 34262 (EFSA-Q-2023-00249)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Lactococcus lactis* DSM 34262 as a technological 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.

6.7 *Lactiplantibacillus plantarum* DSM 34271 (EFSA-Q-2023-00250)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Lactiplantibacillus plantarum* DSM 34271 as a technological 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 *Loigolactobacillus coryniformis* DSM34345 for all animal species (EFSA-Q-2023-00362)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Loigolactobacillus coryniformis* DSM34345 as a technological 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 Calcium D-pantothenate for all animal species (EFSA-Q-2023-00452)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of calcium D-pantothenate as a nutritional additive for all animal species.

The draft opinion was discussed in the 173rd Plenary meeting, but the opinion could not be adopted as the public consultation on the non-confidential version of the application was ongoing. Following the closure of the public consultation, the Panel unanimously adopted the opinion.

6.10 Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Caraway seed oil (EFSA-Q-2024-00305)

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

6.11 Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Celery seed oil (EFSA-Q-2024-00060)

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

7. Other scientific topics for information/discussion

7.1 Assessment of feed additives consisting of or containing nanoparticles

A discussion took place on the criteria to define when the characterisation of the faction of small particles including nanoparticles of feed additives is not necessary. The Panel agreed on these criteria, which are detailed in the Annex.

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-2024-00316	L-Isoleucine as nutritional additive for all animal species
EFSA-Q-2024-00319	Vitamin A (3a672), in form of retinyl acetate, retinyl palmitate & retinyl propionate as nutritional additive for all animal species
EFSA-Q-2024-00320	Biotin as nutritional additives for all animal species
EFSA-Q-2024-00329	*Enterococcus lactis* NCIMB 10415 (1k20601) as technological additive for all animal species
EFSA-Q-2024-00336	Guanidinoacetic acid (GAA) (4d372) and GAA preparation (4d372i) as zootechnical additive for turkeys for fattening and turkeys reared for breeding and laying
EFSA-Q-2024-00394	Taurine (3a370) as nutritional additive for all animal species
EFSA-Q-2024-00395	*Bacillus velezensis* ATCC PTA-6737 (4b1823) as zootechnical additive for laying hens and other birds kept for egg production or breeding
EFSA-Q-2024-00407	Vitamin B1 as thiamine mononitrate (3a821) and thiamine hydrochloride (3a820) as nutritional additive for all animal species
EFSA-Q-2024-00408	Betaine as betaine anhydrous (3a920) and betaine hydrochloride (3a925) as nutritional additive for all animal species

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-2023-00436	L-Cystine produced with *Escherichia coli* K12 DSM 34232 as nutritional and sensory additive for all animal species	10/06/2024
EFSA-Q-2023-00437	Preparation of L-cysteine and L-cysteine hydrochlorides as nutritional and sensory additive for all animal species	10/06/2024
EFSA-Q-2023-00547	L-Valine produced with *Corynebacterium glutamicum* KCCM 80366 as nutritional additive for all animal species	31/05/2024
EFSA-Q-2023-00585	*Vaccinium macrocarpon* extract (w.b.) for dogs and cats	11/06/2024
EFSA-Q-2024-00006	Citric acid (anhydrous and monohydrate) as technological additive for all animal species	03/06/2024

EFSA-Q number	Subject	Valid on
EFSA-Q-2024-00008	*Bacillus velezensis* CECT 5940 (EC ID 4b1822) as zootechnical additive for laying hens and other bird species kept for egg production purposes	29/05/2024
EFSA-Q-2024-00033	L-Isoleucine (3c381) produced with *Escherichia coli* FERM ABP-10641 as a nutritional additive for all animal species	11/06/2024
EFSA-Q-2024-00035	*Bacillus licheniformis* DSM 28710 as zootechnical additive for pigs	31/05/2024
EFSA-Q-2024-00091	L-Isoleucine (min. 90%, min. 65%) produced with *Corynebacterium glutamicum* KCCM80388 as nutritional and sensory additive for all animal species	10/06/2024
EFSA-Q-2024-00121	L-Valine produced with *Escherichia coli* CNCM I-5911 as nutritional additive for all animal species	07/06/2024
EFSA-Q-2024-00223	Potassium iodide (3b201) and calcium iodate anhydrous (3b202) for all animal species	31/05/2024

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

EFSA-Q number	Subject
EFSA-Q-2024-00317	*Enterococcus lactis* NCIMB 11181 (4b1708) as zootechnical additive for chickens for fattening, chickens reared for laying and other poultry species for fattening or reared for laying and ornamental birds

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

9.1 Scientific Committee

Not discussed.

9.2 Scientific Panel(s) including their Working Groups

Not discussed.

9.3 EFSA

Not discussed

9.4 European Commission/EURL

Not discussed.

10. Any other business

10.1 Next meeting

The next meeting will be held on 2-4 July 2024 in Parma.

10.2 Closure of the meeting and the mandate of the Panel

The Chair of the Panel closed the last Plenary meeting of the current Panel's mandate thanking all the experts as well as the staff of the FEED Team for their work and dedication during the last six years.

Annex

Criteria to establish when the characterisation of the fraction of small/nano particles in feed additives is not needed

In its former meeting, the FEEDAP Panel discussed the implementation of the *Scientific Committee Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health* (EFSA Scientific Committee, 2021a) and the *Scientific Committee Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles for the safety assessments of feed additives* (EFSA Scientific Committee, 2021b).

The FEEDAP Panel agreed that:

- there is a need for practical guidance tailored to feed additive safety assessments 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 risk assessment of feed additives will follow the currently available sectorial guidance documents, while the characterisation of feed additives will be continued to determine the presence of small particles, including nano particles, based on the *Guidance on technical requirements* and the safety assessment will follow the currently available sectorial guidance documents.

As a follow-up of this decision, the FEEDAP Panel elaborated a series of criteria with the aim to define those active substances used as/in feed additives for which there is no need to characterise the potential presence of small particles including nanoparticles.

The below exclusions do not apply to feed additives consisting of or containing engineered nanomaterials, as well as in cases when the manufacturing process includes steps that may lead to the presence of small particles including nanoparticles.

In principle, there is no need to characterise the fraction of small particles including nanoparticles if:

- the active component(s) of the feed additive consists only of protein(s);
- the active substance is absorbed as a normal constituent of body fluids or tissues;
- the active substance is naturally present in food or feedingstuffs;
- the active substance is highly soluble in water (> 33 g/L)
- the additive is comprised of, or contains, the active substance in fully solubilised form in relevant aqueous or oily medium;
- the solubility data indicate that the active substance will be fully solubilised in the feed matrix including premixtures and formulations of the additive considering the maximum proposed use level, or in the gastrointestinal tract of the target species on the basis of dissolution at the maximum proposed use level;
- in case of possible uptake of a lipophilic active substance from the gastrointestinal tract as particles, it can be expected that the particles will partition into the lipophilic cell compartments, suggesting that systemic distribution of particles is unlikely to occur in the target animal body (based on information on Kow, solubility in organic solvents/oils, evidence from existing ADME and/or toxicological studies).

In addition, the Panel notes that in line with the *Guidance on technical requirements* (EFSA Scientific Committee, 2021b), there is no need to characterise the fraction of small particles including nanoparticles if the active component(s) of the feed additive consists only of microorganism(s).

For measurement of parameters in the bullet points above (e.g. solubility in water), the methodologies detailed in the EFSA Nano Guidance documents should be followed (EFSA Scientific Committee, 2021a;b).

For substances not excluded above, the applicant should provide analysis of the particle size, particle shape and number-based size distribution via the method indicated in the Scientific

Committee Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (i.e., quantitative EM) following the methodology indicated in the EFSA Nano Guidance documents (EFSA Scientific Committee, 2021a;b).

The Panel notes that these criteria do not preclude the request of additional information on the characterization of the fraction of small particles/nanoparticles when the Panel considers there are reasons for it.

The Panel might update this approach when practical guidance on the risk assessment of nanoparticles present in feed additives will be available.