

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



167th Plenary meeting 11-12 May 2023

09:00-18:00 / 09:00-18:00

MINUTES – agreed on 29 May 2023

Location: Online

Participants:

- **Panel Members:**

Giovanna Azimonti, Vasileios Bampidis, 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, Yolanda Sanz¹, 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 Gilsean, 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.

RAL Unit: Laure Excoffon²

- **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 "AQ02 (*Lactobacillus plantarum* CECT 8350 and *Lactobacillus reuteri* CECT 8700) for suckling piglets ([EFSA-Q-2022-00353](#))".

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 Interest related to the issues discussed in this meeting have been identified during the

¹ Present only on 12 May 2023

² For item 7.2.a

³ [Policy on Independence](#)

⁴ [Competing Interest Management](#)



screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Report on written procedures since the 166th FEEDAP Plenary meeting

The minutes of the 166th FEEDAP Plenary meeting were agreed by written procedure on 13 April 2023.⁵

5. Scientific topics for discussion

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

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

5.2. Potassium ferrocyanide (potassium hexacyanoferrate trihydrate) for all animal species ([EFSA-Q-2013-00529](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of potassium ferrocyanide (potassium hexacyanoferrate trihydrate) as a technological additive for all animal species.

The draft opinion was originally adopted in the 166th Plenary meeting of the FEEDAP Panel. However, after adoption, it was identified that some data originally submitted by the applicant were not considered in the assessment. Therefore, the Panel agreed to withdraw the adoption of the opinion. An updated draft opinion considering all the information was discussed, focusing on the safety of the additive. The Panel unanimously adopted the opinion.

5.3. Chemically defined flavourings from Chemical Group 29 - thiazoles, thiophene, thiazoline and thienyl derivatives: 4-methyl-5-vinylthiazole [15.018] for all animal species and categories ([EFSA-Q-2016-00184](#))

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of chemically defined flavourings from Chemical Group 29 - thiazoles, thiophene, thiazoline and thienyl derivatives: 4-methyl-5-vinylthiazole [15.018] 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.

5.4. 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.

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



The draft opinion was discussed. Further discussion is needed.

5.5. Amoklor™ (ammonium chloride) for all ruminants, sows for urinary health, cats and dogs ([EFSA-Q-2020-00815](#))

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 Amoklor™ (ammonium chloride) as a zootechnical additive for all ruminants, sows for urinary health, cats and dogs.

The draft opinion was originally adopted in the 164th Plenary meeting of the FEEDAP Panel. However, after adoption, it was identified that an aspect of the safety assessment had not been fully considered. Therefore, the Panel agreed to withdraw the adoption of the opinion. An updated draft opinion was discussed, focusing on the safety of the additive for the environment. The Panel unanimously adopted the opinion.

5.6. 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 and minor poultry species for fattening and chickens reared for laying.

The draft opinion was discussed. The Panel identified the need to request additional information to the applicant.

5.7. 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. Further discussion is needed.

5.8. *Lentilactobacillus buchneri* BioCC 203 DSM 32650 for all animal species ([EFSA-Q-2021-00381](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Lentilactobacillus buchneri* BioCC 203 DSM 32650 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.

5.9. Sangrovit® Extra (preparation of *Macleaya cordata* extract and leaves) for all poultry species ([EFSA-Q-2021-00454](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Sangrovit® Extra (preparation of *Macleaya cordata* extract and leaves) as a zootechnical additive for all poultry species.

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

5.10. 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 *Trichoderma reesei* (ATCC 74444)) for poultry



for fattening other than turkeys for fattening, poultry for laying, turkeys for fattening and piglets (weaned) ([EFSA-Q-2021-00498](#))

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 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 *Trichoderma reesei* (ATCC 74444)) as a zootechnical additive for poultry for fattening other than turkeys for fattening, poultry for laying, turkeys for fattening and piglets (weaned).

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

5.11. Elancoban[®] (monensin sodium) for chickens for fattening, chickens reared for laying, turkeys ([EFSA-Q-2021-00537](#))

EFSA was requested to deliver an opinion on the safety of Elancoban[®] (monensin sodium) as a coccidiostat for chickens for fattening, chickens reared for laying, turkeys based on the additional data submitted by the applicant.

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

5.12. Nutrixtend Optim (beta-mannanase produced by *Aspergillus niger* (CBS 120604)) for all poultry for fattening ([EFSA-Q-2021-00549](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Nutrixtend Optim (beta-mannanase) produced by *Aspergillus niger* (CBS 120604) as a zootechnical additive for all poultry for fattening.

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

5.13. 25-Hydroxycholecalciferol for all pigs, all poultry for fattening and ornamental birds, and other poultry species ([EFSA-Q-2021-00641](#))

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of 25-hydroxycholecalciferol as a nutritional additive for all pigs, all poultry for fattening and ornamental birds, and other poultry species.

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

5.14. Thaumatin (2b957) for all animal species ([EFSA-Q-2021-00739](#))

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of thaumatin (2b957) as a sensory 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.

5.15. *Lactiplantibacillus plantarum* AK 5106, 5M-1R – DSM 23375 for all animal species ([EFSA-Q-2021-00741](#))

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Lactiplantibacillus plantarum* AK 5106, 5M-1R – DSM 23375 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.



5.16. *Pediococcus pentosaceus* NCIMB 30168 for all animal species ([EFSA-Q-2022-00204](#))

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Pediococcus pentosaceus* NCIMB 30168 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. AQ02 (*Lactobacillus plantarum* CECT 8350 and *Lactobacillus reuteri* CECT 8700) for suckling piglets ([EFSA-Q-2022-00353](#))

EFSA was requested to deliver an opinion on the efficacy of AQ02 (*Lactobacillus plantarum* CECT 8350 and *Lactobacillus reuteri* CECT 8700) as a zootechnical additive for suckling piglets.

The draft opinion was originally adopted in the 165th Plenary meeting of the FEEDAP Panel. However, after adoption, an error was identified which had an impact on the assessment of the data. Therefore, the Panel agreed to withdraw the adoption of the opinion. An updated draft opinion was discussed, focusing on the efficacy of the additive. The Panel unanimously adopted the opinion.

5.18. Xygest™ HT (endo-1,4-beta-xylanase EC 3.2.1.8) for poultry ([EFSA-Q-2022-00807](#))

EFSA was requested to deliver an opinion on the efficacy of Xygest™ HT (endo-1,4-beta-xylanase EC 3.2.1.8) as a zootechnical additive for poultry based on the additional data provided by the applicant.

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

5.19. L-Lysine monohydrochloride, concentrated liquid L-lysine, concentrated liquid L-lysine monohydrochloride for all animal species ([EFSA-Q-2023-00018](#))

EFSA was requested to deliver an opinion on the presence of recombinant DNA in L-lysine monohydrochloride, concentrated liquid L-lysine, concentrated liquid L-lysine monohydrochloride as a nutritional and sensory additive for all animal species.

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

5.20. *Lactobacillus farciminis* CNCM MA67/4R (now CNCM I-3740) for chickens for fattening and turkeys for fattening ([EFSA-Q-2023-00044](#))

EFSA was requested to deliver an opinion on the efficacy of *Lactobacillus farciminis* CNCM MA67/4R (now CNCM I-3740) as a zootechnical additive for chickens for fattening and turkeys for fattening.

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

5.21. BA-KING® (*Bacillus amyloliquefaciens* TOA5001 (NITE BP-01844)) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all minor avian species



(including also sporting, ornamental and exotic birds) ([EFSA-Q-2023-00077](#))

EFSA was requested to deliver an opinion on the efficacy of BA-KING® (*Bacillus amyloliquefaciens* TOA5001 (NITE BP-01844)) as a zootechnical additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all minor avian species (including also sporting, ornamental and exotic birds).

The draft opinion was discussed focusing on the 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-2023-00207	L-isoleucine for all animal species
EFSA-Q-2023-00249	<i>Lactococcus lactis</i> DSM 34262
EFSA-Q-2023-00250	<i>Lactiplantibacillus plantarum</i> DSM 34271
EFSA-Q-2023-00251	Preparation of endo-1,3(4)-beta-glucanase (EC 3.2.1.6) produced by <i>Trichoderma reesei</i> (CBS 126896)
EFSA-Q-2023-00252	<i>Enterococcus faecium</i> DSM 22502
EFSA-Q-2023-00253	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 / Endo-1,4-beta-xylanase EC 3.2.1.8 (4a1604i) Rovabio Excel
EFSA-Q-2023-00254	Preparation of 6-phytase (EC 3.1.3.26) produced by <i>Trichoderma reesei</i> (CBS 126897)
EFSA-Q-2023-00255	<i>Saccharomyces cerevisiae</i> NCYC R618 (Benesacc)
EFSA-Q-2023-00262	CAPSOZYME SB PLUS (alpha-galactosidase and endo-1,4-beta-xylanase; additive ID no: 4a33) for turkeys
EFSA-Q-2023-00276	<i>Levilactobacillus brevis</i> DSM 23231
EFSA-Q-2023-00298	<i>Lactobacillus plantarum</i> 14D/CSL - CECT 4528 for all animal species
EFSA-Q-2023-00325	Enterosure (<i>Bacillus velezensis</i> ATCC PTA-6737, ATCC PTA-127114, <i>Bacillus licheniformis</i> ATCC-127113) for all growing avian species

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-2022-00324	<i>Lactiplantibacillus plantarum</i> NCIMB 30094 for all animal species	24/03/2023
EFSA-Q-2022-00342	<i>Lactiplantibacillus plantarum</i> NCIMB 30148 for all animal species	23/03/2023
EFSA-Q-2022-00343	<i>Lactiplantibacillus plantarum</i> NCIMB 41028 for all animal species	22/03/2023



EFSA-Q number	Subject	Valid on
EFSA-Q-2022-00357	Sangrovit® Extra (Preparation of <i>Macleaya cordata</i> extract and leaves) for suckling and weaned piglets and other growing Suidae	20/03/2023
EFSA-Q-2022-00402	Sodium Bisulphate (SBS, 1j514ii) for food-producing animals, pets, other non-food animals	20/03/2023
EFSA-Q-2022-00512	Niacinamide (3a315) for all animal species	17/04/2023
EFSA-Q-2022-00746	PB6 for all growing birds and with halofuginone	18/04/2023
EFSA-Q-2022-00778	<i>Lentilactobacillus</i> (<i>Lactobacillus</i>) <i>buchneri</i> LN4637/ATCC PTA-2494 for all animal species	02/05/2023
EFSA-Q-2022-00779	Tartrazine (2a102) for freshwater fish	31/03/2023
EFSA-Q-2022-00780	<i>Lentilactobacillus</i> (<i>Lactobacillus</i>) <i>buchneri</i> LN40177 / ATCC PTA-6138 for all animal species	02/05/2023
EFSA-Q-2022-00781	Ponceau 4R (2a124) for freshwater fish	31/03/2023
EFSA-Q-2022-00792	Cobalt (compounds: cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate) for bovines with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals	22/03/2023
EFSA-Q-2022-00857	Zinc-L-Selenomethionine (3b818) for all animal species	24/03/2023
EFSA-Q-2022-00880	Sodium propionate (1k281) for all species	26/04/2023
EFSA-Q-2023-00110	L-Selenomethionine (3b815) for all animal species	25/04/2023

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-2023-00018	L-Lysine monohydrochloride, concentrated liquid L-lysine, concentrated liquid L-lysine monohydrochloride for all animal species
EFSA-Q-2023-00078	Xanthan gum for all animal species
EFSA-Q-2023-00165	Nimicoat (Carvacrol) for piglets (weaned)
EFSA-Q-2023-00186	BIO-THREE® (<i>Bacillus subtilis</i> TO-A (BS), <i>Enterococcus faecium</i> T-110 (EF), <i>Clostridium butyricum</i> TO-A (CB)) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor poultry species
EFSA-Q-2023-00231	Propyl gallate 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

- a. The NDA Panel has launched a public consultation on the “draft scientific opinion on the Tolerable Upper Intake Level for vitamin D, including the derivation of a conversion factor for calcidiol monohydrate”. The public consultation can be accessed on [EFSA’s website](#) and will remain open until 05/06/2023.
- b. The NIF Unit has launched a public consultation on its protocol for the evaluation of the safety in use of plant preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C.Presl) in the context of the procedure initiated by the European Commission under Article 8 (2) of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. The consultation can be accessed on [EFSA’s website](#) and will be open until 12/06/2023.

7.2. EFSA

- a. A member of the RAL unit presented the Panel the new microsite with information and resources to support collaboration and communication with experts collaborating with EFSA.

7.3. European Commission/EURL

- a. The European Union Reference Laboratory (EURL) has recently finished an addendum of the EURL evaluation report for:
 - i) *Duddingtonia flagrans* IAH 1297 linked to FAD-2016-0067 (EFSA-Q-2016-00868); the addendum referred to enumeration of the active substance (viable spores of *Duddingtonia flagrans* IAH 1297) in compound feed. The EURL recommended for official control the single-laboratory validated and verified method proposed for the enumeration of the active substance (viable spores of *Duddingtonia flagrans* IAH 1297) in compound feed;
 - ii) Potassium diformate linked to FAD-2008-0044 (EFSA-Q-2008-00693); the addendum referred to the determination of potassium diformate (as total formic acid) in the feed additive, premixtures, compound feed and water. The EURL recommended for official control the ring-trial validated EN 17294 method based on ion chromatography coupled to conductivity detection (IC-CD) for the determination of potassium diformate (as total formic 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 Safety for target species

In some applications data from toxicological studies is used to conclude on target species. The guidance on the [safety for the target species](#) provides in its Table 1 default values that allow for the calculation of maximum safe value in feed for several species/categories. For those species/categories for which default values are not indicated in the guidance, the applicant can propose values for daily feed intake and body weight. In the absence of default values the FEEDAP Panel considers that conclusions may be derived as per the table below.



Maximum safe level established for	Species to which the maximum safe level can be applied to¹
Chickens for fattening	Other poultry for fattening or reared for laying/reproduction; ornamental birds and other avian species at the same physiological stage
Laying hens	Other laying/reproductive birds
Piglets	All pigs (Suidae) for meat production or reared for reproduction
Sows lactating	All pigs (Suidae) for reproduction
Cattle for fattening	Other ruminants for fattening or reared for milk production/reproduction and camelids at the same physiological stage
Dairy cows	Other ruminants and camelids for milk production or reproduction
Salmons	Other fin fish
Horses	Other Equidae

¹ Species other than those listed in Table 1 of the guidance on the [safety for the target species](#)

In the absence of information on other species, the lowest value obtained from the calculations will be applied.

9. Any other business

9.1 New Working Group on characterisation of feed additives

The Panel agreed on the need for a new Working Group on Characterisation of feed additives, which will be responsible for the assessment of the data submitted on the identity and characterisation of feed additives for which an application is submitted under Regulation (EC) No 1831/2003 (except microorganisms).