



FEED UNIT

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

### MINUTES OF THE 162<sup>nd</sup> FEEDAP PLENARY MEETING

Webconference, 29-30 June 2022

(Agreed by written procedure on 5 July 2022)

### **Participants**

#### Panel Members:

Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon 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:

Jürgen Gropp<sup>1</sup>

#### European Commission

N/A

#### EFSA:

**FEED Team**: Angelica Amaduzzi, Montserrat Anguita, Rosella Brozzi, Joana Firmino, Jaume Galobart, Yolanda García Cazorla, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Paola Manini, Rita Navarrete, Alberto Navarro Villa, Jordi Ortuño, Daniel Pages, Elisa Pettenati, Fabiola Pizzo, Daniel Plaza, Anita Radovnikovic, Martina Reitano, Joana Revez, Barbara Rossi, Jordi Tarrés-Call, Frank Verdonck and Maria Vittoria Vettori.

#### Others:

N/A

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Yolanda Sanz. Angelica Amaduzzi, Joana Firmino and Alberto Navarro Villa were also welcomed as Scientific Officers in the FEED team.

Attended for item 5.15 only





### 2. Adoption of agenda

The agenda was adopted without modifications.

#### 3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

### 4. Report on written procedures since the 161st FEEDAP Plenary meeting

The minutes of the 161st FEEDAP Plenary meeting were agreed by written procedure on 10 May 20224.

### 5. Scientific topics for discussion

5.1. Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Ferula assa-foetida oil for cats and dogs (EFSA-Q-2010-01286, EFSA-Q-2022-00404)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of *Ferula assa-foetida* oil as a sensory additive for cats and dogs.

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The opinion will be presented for adoption in a future plenary.

5.2. Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Dill herb oil for cats and dogs (EFSA-Q-2010-01286, EFSA-Q-2022-00405)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of dill herb oil as a sensory additive for cats and dogs.

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The opinion will be presented for adoption in a future plenary.

5.3. Botanically defined flavourings from Botanical Group 06 - Laurales, Magnoliales, Piperales for all animal species and categories: Cassia oil (EFSA-Q-2010-01296, EFSA-Q-2022-00104)

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

3 Competing Interest Management

2

Policy on Independence

<sup>4 &</sup>lt;a href="https://www.efsa.europa.eu/sites/default/files/2022-05/feedap20220504">https://www.efsa.europa.eu/sites/default/files/2022-05/feedap20220504</a> m.pdf





The draft opinion was discussed focusing on the safety of the additive. The opinion will be presented for adoption in a future plenary.

# 5.4. Botanically defined flavourings from Botanical Group 06 - Laurales, Magnoliales, Piperales for all animal species and categories: Cinnamon oil (EFSA-Q-2010-01296, EFSA-Q-2022-00105)

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

The draft opinion was discussed focusing on the safety of the additive. The opinion will be presented for adoption in a future plenary.

## 5.5. Botanically defined flavourings from Botanical Group 06 - Laurales, Magnoliales, Piperales for all animal species and categories: Pepper oil and Pepper oleoresin (EFSA-Q-2010-01296, EFSA-Q-2022-00106)

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

The draft opinion was discussed focusing on the safety of the additive. The opinion will be presented for adoption in a future plenary.

### 5.6. Glyceryl polyethyleneglycol ricinoleate (PEG castor oil) for all animal species (EFSA-Q-2012-01000)

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of glyceryl polyethyleneglycol ricinoleate (PEG castor oil) 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.

#### 5.7. Locust bean gum for all animal species (EFSA-Q-2013-01023)

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of locust bean gum 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.

### 5.8. Tocopheryl phosphate mixture (TPM®) for all animal species (<u>EFSA-Q-2017-00743</u>)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of tocopheryl phosphate mixture (TPM®) 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 unanimously adopted the opinion.

### 5.9. Aviax® 5% (semduramicin sodium) for chickens for fattening (<u>EFSA-Q-2019-00813</u>)

EFSA was requested to deliver an opinion on the safety of Aviax $^{\otimes}$  5% (semduramicin sodium) as a coccidiostat for chickens for fattening based on the additional information provided by the applicant.





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

5.10. Probiotic Lactina (Preparation of Enterococcus faecium NBIMCC 8270, Lactobacillus acidophilus NBIMCC 8242, Lactobacillus helveticus NBIMCC 8269, Lactobacillus delbrueckii ssp. lactis NBIMCC 8250, Lactobacillus delbrueckii ssp. bulgaricus NBIMCC 8244 and Streptococcus thermophilus NBIMCC 8253) for cats and dogs (EFSA-Q-2020-00690)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Probiotic Lactina (Preparation of *Enterococcus faecium* NBIMCC 8270, *Lactobacillus acidophilus* NBIMCC 8242, *Lactobacillus helveticus* NBIMCC 8269, *Lactobacillus delbrueckii* ssp. *lactis* NBIMCC 8250, *Lactobacillus delbrueckii* ssp. *bulgaricus* NBIMCC 8244 and *Streptococcus thermophilus* NBIMCC 8253) as a zootechnical additive for cats and dogs.

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

5.11. Biomin® DC-P (preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol) for all avian species (<u>EFSA-Q-2020-00835</u>)

This question refers to the authorisation under Article 4 and the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of Biomin® DC-P (preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol) as a zootechnical additive 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.

5.12. Alpha-amylase from Bacillus amyloliquefaciens DSM 9553, Bacillus amyloliquefaciens NCIMB 30251, Aspergillus oryzae CBS 585.94 and Aspergillus oryzae ATTC SD-5374, endo-1,4-beta-glucanase from Trichoderma reesei ATCC PTA-10001, Trichoderma reesei ATCC SD-6331 and Aspergillus niger CBS 120604, endo-1,4-beta-xylanase from Trichoderma koningii MUCL 39203 and Trichoderma longibrachiatum CBS 614.94 and endo-1,3(4)-beta-glucanase from Aspergillus tubingensis MUCL 39199 for all animal species (EFSA-Q-2020-00836)

EFSA was requested to deliver an opinion on the characterisation and efficacy of alphaamylase from *Bacillus amyloliquefaciens* DSM 9553, *Bacillus amyloliquefaciens* NCIMB 30251, *Aspergillus oryzae* CBS 585.94 and *Aspergillus oryzae* ATTC SD-5374, endo-1,4-beta-glucanase from *Trichoderma reesei* ATCC PTA-10001, *Trichoderma reesei* ATCC SD-6331 and *Aspergillus niger* CBS 120604, endo-1,4-beta-xylanase from *Trichoderma koningii* MUCL 39203 and *Trichoderma longibrachiatum* CBS 614.94 and endo-1,3(4)-beta-glucanase from *Aspergillus tubingensis* MUCL 39199 as a technological additive for all animal species based on the additional information provided by the applicant.

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





### 5.13. *Pediococcus acidilactici* CNCM I-4622 for all animal species (<u>EFSA-Q-2020-00839</u>)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Pediococcus acidilactici* CNCM I-4622 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.

### 5.14. Xygest<sup>™</sup> HT (endo-1,4-beta-xylanase EC 3.2.1.8) for poultry (<u>EFSA-Q-2021-00098</u>)

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

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

### 5.15. SGE (Solanum glaucophyllum leaf extract) for dairy cows for milk production and other dairy ruminants (EFSA-Q-2021-00239)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of SGE (*Solanum glaucophyllum* leaf extract) as a nutritional additive for dairy cows for milk production and other dairy ruminants.

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

### 5.16. PP102I (*Bifidobacterium longum* CNCM 1-5642) for cats and dogs (<u>EFSA-Q-2021-00249</u>)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of PP102I (*Bifidobacterium longum* CNCM 1-5642) as a zootechnical additive for dairy cows for milk production and other dairy ruminants.

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

# 5.17. Xylamax (endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Komagaetella phaffii* xyl-2 (DSM 33574)) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all minor avian species (<u>EFSA-Q-2021-00254</u>)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Xylamax (endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Komagaetella phaffii* xyl-2 (DSM 33574)) as a zootechnical additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all minor avian species.

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

### 5.18. L-Arginine produced by *Corynebacterium glutamicum* CGMCC 20516 for all animal species (EFSA-Q-2021-00494)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-arginine produced by *Corynebacterium glutamicum* CGMCC 20516 as a nutritional additive for chickens 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.

### 5.19. Levucell<sup>®</sup> SC (*Saccharomyces cerevisiae* CNCM I-1077) for dairy cows, cattle for fattening, minor ruminant species and camelids (EFSA-Q-2021-00527)

EFSA was requested to deliver an opinion on the safety and efficacy of Levucell® SC (*Saccharomyces cerevisiae* CNCM I-1077) as a zootechnical additive for dairy cows, cattle for fattening, minor ruminant species and camelids based on the additional information provided by the applicant.

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

### 5.20. *Pediococcus pentosaceus* DSM 32292 for all animal species (<u>EFSA-Q-2021-00530</u>)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Pediococcus pentosaceus* DSM 32292 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.

### 5.21. Lactobacillus reuteri DSM 32203 for dogs (EFSA-Q-2021-00534)

EFSA was requested to deliver an opinion on the efficacy of *Lactobacillus reuteri* DSM 32203 as a zootechnical additive for dogs based on the additional information provided by the applicant.

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

#### 5.22. Lactobacillus reuteri DSM 32264 for cats (EFSA-O-2021-00633)

EFSA was requested to deliver an opinion on the efficacy of *Lactobacillus reuteri* DSM 32264 as a zootechnical additive for cats based on the additional information provided by the applicant.

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-2022-00316	TechnoSpore 50 ( <i>Weizmannia coagulans</i> DSM 32016 (formerly <i>Bacillus coagulans</i> DSM 32016)) for poultry for fattening, ornamental birds, suckling and weaned Suidae piglets





EFSA-Q-Number	Subject	
EFSA-Q-2022-00317	Lactiplantibacillus plantarum NCIMB 30083 (formerly Lactobacillus plantarum) NCIMB 30083 for all animal species	
EFSA-Q-2022-00318	Balancius® Muramidase (EC 3.2.1.17) for laying hens	
EFSA-Q-2022-00320	PB6 Bacillus velezensis ATCC PTA-6737 for pigs	
EFSA-Q-2022-00321	Biomin® C5 (Preparation of Enterococcus faecium DSM 33761, Pediococcus acidilactici DSM 33758, Bifidobacterium animalis DSM 16284, Limosilactobacillus reuteri DSM 33751 and Ligilactobacillus salivarius DSM 16351) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species other than laying species	
EFSA-Q-2022-00322	Lactiplantibacillus plantarum NCIMB 30084 for all animal species	
EFSA-Q-2022-00323	Xygest <sup>™</sup> HT (endo-1,4-beta-xylanase (EC 3.2.1.8)) for all pigs	
EFSA-Q-2022-00324	Lactiplantibacillus plantarum NCIMB 30094 for all animal species	
EFSA-Q-2022-00325	GalliPro® Fit ( <i>Bacillus subtilis</i> DSM 32324, <i>Bacillus subtilis</i> DSM 32325 and <i>Bacillus amyloliquefaciens</i> DSM 25840) for all poultry species for fattening or reared for laying or reared for breeding	
EFSA-Q-2022-00326	Huvezym neXo (multi-enzyme product with endo 1,4 betaxylanase, endo 1,4 betaglucanase and xyloglucan-specific-endo-beta-1,4-glucanase activities) for sows, pigs for fattening and minor pig species for fattening or reproduction	
EFSA-Q-2022-00340	Pediococcus acidilactici CNCM I-4622 for all insect species and categories	
EFSA-Q-2022-00350	KemTRACE Chromium (Chromium propionate) for all growing birds	
EFSA-Q-2022-00354	Interban (narasin (100 mg/g) and dicalzuril (2 mg/g)) for chickens for fattening and chickens reared for laying	
EFSA-Q-2022-00355	aXiphen AB (Phenylcapsaicin) for chickens for fattening	
EFSA-Q-2022-00356	Methionine (DL-methionine; hydroxy analogue of methionine; calcium salt of hydroxy analogue of methionine) for all animal species and Methionine (DL-methionine protected with copolymer vinylpyridine/styrene; DL-methionineprotected with ethylcellulose; Isopropyl ester of hydroxy analogue of methionine) for ruminants	
EFSA-Q-2022-00357	Sangrovit® Extra (Preparation of <i>Macleaya cordata</i> extract and leaves) for suckling and weaned piglets and other growing Suidae	
EFSA-Q-2022-00373	Saccharomyces cerevisiae Canobios-BL for cats and 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-2021-00449	Microsaf ( <i>Bacillus velezensis</i> ( <i>amyloliquefaciens</i> ) NRRL B-67647, <i>Bacillus pumilus</i> NRRL B-67648, <i>Bacillus licheniformis</i> NRRL B-67649) for chickens for fattening and other poultry for fattening (e.g. turkeys, ducks, geese, pheasants, quail, guinea fowl, ostrich) and ornamental birds	09/06/2022
EFSA-Q-2022-00017	Lactobacillus (Lactiplantibacillus) plantarum DSM 5284 - ATCC 55944 for all animal species	17/06/2022
EFSA-Q-2022-00019	Lactobacillus (Lactiplantibacillus) plantarum DSM 4786 - DSM 18114 for all animal species	17/06/2022
EFSA-Q-2022-00020	Lactobacillus (Lactiplantibacillus) plantarum DSM 4785 - DSM 18113 for all animal species	17/06/2022
EFSA-Q-2022-00021	Lactobacillus (Lactiplantibacillus) plantarum DSM4784- ATCC53187- DSM18112 for all animal species	17/06/2022
EFSA-Q-2022-00022	Lactobacillus (Lactiplantibacillus) plantarum ATCC PTA-6139 for all animal species	17/06/2022

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

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

#### 7.1. Scientific Committee/Scientific Panels

Not discussed

#### 7.2. EFSA

The Panel was informed on the technical meeting with industry that took place on 15 June to gather input on the ongoing work for the update of the guidance on user safety and on the future steps.

#### 7.3. European Commission

Not discussed.

### 8. Other scientific topics for information/or discussion

#### Skin sensitisation potential of microorganisms

The current guidance on the assessment of the safety of feed additives for the user requires that "Tests for skin and eye irritation and for skin sensitisation potential should be performed using the appropriate form of the additive". However, the Panel notes that the OECD test guidelines available at present are designed to assess the skin sensitisation potential of chemical substances only and that currently no validated assays for assessing the sensitisation potential of microorganisms are available. In order to reduce animal testing and in line with the 3R principles, the Panel agreed that for





microorganisms no skin sensitisation studies should be provided by the applicants in the context of applications for the authorisation of feed additives. The assessment of the sensitisation potential of microorganisms used as feed additives will be reconsidered in the ongoing update of the FEEDAP Panel Guidance of the assessment of safety for the users.

### 9. Any other business

Not discussed.