

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

## MINUTES OF THE 151<sup>st</sup> FEEDAP PLENARY MEETING

**Webconference, 27-28 January 2021**

**(Agreed by written procedure on 4 February 2021)**

### 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, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

■ **Hearing Experts:**

Not applicable

■ **European Commission**

Not applicable

■ **EFSA:**

**Feed Unit:** Angelica Amaduzzi, Montserrat Anguita, Jaume Galobart, Lucilla Gregoretti, Davide Guerra, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini, Elisa Pettenati, Fabiola Pizzo, Joana Revez, Jordi Tarrés-Call, Frank Verdonck and Maria Vittoria Vettori.

**REPRO Department:** Guilhem de Seze<sup>1</sup>

**TS Unit:** Claudia Paoletti<sup>1</sup>

■ **Others:**

Not applicable

### 1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

<sup>1</sup> Participated on 28 January for item 7.2.a



This meeting, originally scheduled as a physical meeting, was converted into a webconference to avoid traveling to Parma in line with the measures established to reduce the risk of coronavirus infection.

## 2. Adoption of agenda

The agenda was adopted after deletion of the topics on "*Lactobacillus animalis* LA51 (ATCC PTA-6750) (EFSA-Q-2016-00713)" and "*Propionibacterium freudenreichii* ssp. *shermanii* ATCC PTA-6752 (PF24) for all animal species (EFSA-Q-2017-00613)".

## 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.

Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

## 4. Report on written procedures since the 150<sup>th</sup> FEEDAP Plenary meeting

The minutes of the 150<sup>th</sup> FEEDAP Plenary meeting were agreed by written procedure on 24 November 2020<sup>4</sup>.

## 5. Scientific topics for discussion

### 5.1. Tragacanth gum for all animal species (EFSA-Q-2013-01020)

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of tragacanth gum as a technological additive for all animal species.

Given the amount of information missing from the dossier, the Panel is not able to perform an assessment of this application. The Panel unanimously adopted the statement.

### 5.2. *Echinacea angustifolia* DC. extract (Blacksamson echinacea extract) and *Echinacea purpurea* (L.) Moench. extract (Echinacea extract) for cats and dogs (EFSA-Q-2018-00319)

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of *Echinacea angustifolia* DC. extract (Blacksamson echinacea extract) and *Echinacea purpurea* (L.) Moench. extract (Echinacea extract) as a sensory 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.

<sup>2</sup> [Policy on Independence](#)

<sup>3</sup> [Competing Interest Management](#)

<sup>4</sup> <https://www.efsa.europa.eu/sites/default/files/event/2020/150th-plenary-meeting-feedap-panel-open-observers-minutes.pdf>



**5.3. *Garcinia cambogia* Desrouss. (Garcinia extract) for cats and dogs (EFSA-Q-2018-00440)**

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of *Garcinia cambogia* Desrouss. (Garcinia extract) as a sensory 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.

**5.4. *Plantago ovata* L. husk (Fleawort absolute) for cats and dogs (EFSA-Q-2018-00441)**

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of *Plantago ovata* L. husk (Fleawort absolute) as a sensory 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.

**5.5. Ronozyme® ProAct (serine protease EC 3.4.21.- produced by *Bacillus licheniformis* DSM 19670) for chickens for fattening (EFSA-Q-2019-00156)**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Ronozyme® ProAct as a zootechnical additive 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.

**5.6. B-Act® (*Bacillus licheniformis* DSM 28710) for laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds (EFSA-Q-2019-00525)**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of B-Act® (*Bacillus licheniformis* DSM 28710) as a zootechnical additive for laying hens, minor poultry species for laying, poultry species for breeding purposes and ornamental birds.

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

**5.7. Bonvital (*Enterococcus faecium* DSM 7134) for chickens for fattening (EFSA-Q-2019-00741)**

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Bonvital (*Enterococcus faecium* DSM 7134) as a zootechnical additive for chickens for fattening.

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

**5.8. *Clostridium butyricum* FERM BP-2789 for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), piglets (suckling and weaned piglets), minor porcine species (EFSA-Q-2019-00802)**



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 *Clostridium butyricum* FERM BP-2789 as a zootechnical additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), piglets (suckling and weaned piglets), minor porcine species.

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

#### **5.9. Balancius (muramidase) for piglets (weaned) (EFSA-Q-2020-00199)**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Balancius (muramidase) as a zootechnical additive for piglets (weaned).

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

#### **5.10. Manganese chelates of lysine and glutamic acid (ProPath Mn) for all animal species (EFSA-Q-2020-00310)**

EFSA was requested to deliver an opinion on the safety of manganese chelates of lysine and glutamic acid (ProPath Mn) as a nutritional additive for all animal species based on the additional information provided by the applicant.

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

#### **5.11. Deccox® (E756) for chickens for fattening (EFSA-Q-2020-00324)**

EFSA was requested to deliver an opinion on the efficacy of Deccox® (decoquinat) as a coccidiostat for chickens for fattening 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.

#### **5.12. Ferric citrate chelate for piglets (weaned, suckling) and minor porcine species (EFSA-Q-2020-00346)**

EFSA was requested to deliver an opinion on the safety of ferric citrate chelate as a zootechnical additive for piglets (weaned, suckling) and minor porcine species based on the additional information provided by the applicant.

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

#### **5.13. Belfeed B MP/ML (endo-1,4-β-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* LMG S-15136) for sows in order to have benefit in piglets (EFSA-Q-2020-00444)**

EFSA was requested to deliver an opinion on the safety and efficacy of Belfeed B MP/ML (endo-1,4-β-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* LMG S-15136) as a zootechnical additive for sows in order to have benefit in piglets, based on the additional information provided by the applicant.

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



**5.14. L-tryptophan produced by *E. coli* KCCM 80210 for all animal species (EFSA-Q-2020-00499)**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-tryptophan produced by *Escherichia coli* KCCM 80210 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.

**5.15. Coxam® (amprolium hydrochloride) for chickens for fattening and chickens reared for laying (EFSA-Q-2020-00535)**

EFSA was requested to deliver an opinion on the efficacy of Coxam® (amprolium hydrochloride) as a coccidiostat for chickens for fattening and chickens reared for laying 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.

**5.16. ECONASE® XT (endo-1,4-β-xylanase produced by *Trichoderma reesei* CBS 114044) for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (EFSA-Q-2020-00653)**

EFSA was requested to deliver an opinion on the safety of ECONASE® XT (endo-1,4-β-xylanase produced by *Trichoderma reesei* CBS 114044) as a zootechnical additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding based on the additional information provided by the applicant.

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-2020-00767	Axtra® PHY GOLD 30 L, Axtra® PHY GOLD 30 T, Axtra® PHY GOLD 65 G (6-phytase) for all pigs, all poultry species
EFSA-Q-2020-00769	<i>Lactobacillus buchneri</i> DSM 12856 for all animal species and categories
EFSA-Q-2020-00807	AveMix XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for piglets (suckling and weaned piglets)
EFSA-Q-2020-00808	L-Histidine monohydrochloride monohydrate produced by fermentation with <i>E. coli</i> NITE SD 00329 for all animal species
EFSA-Q-2020-00809	Butylated hydroxyanisole (BHA) for cats
EFSA-Q-2020-00814	<i>Pediococcus acidilactici</i> DSM 16243 for all animal species



EFSA-Q-Number	Subject
EFSA-Q-2020-00815	Amoklor™ (ammonium Chloride) for all ruminants, sows for urinary health, cats and dogs
EFSA-Q-2020-00835	Biomin8 DC-P (preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol) for all avian species
EFSA-Q-2020-00837	Coxidin® (monensin sodium (carrier perlite, wheat bran)) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding
EFSA-Q-2020-00838	Riboflavin 5'-phosphate ester monosodium salt (solid form produced after phosphorylation of riboflavin 98%) produced by <i>Bacillus subtilis</i> KCCM-10445 for all animal species
EFSA-Q-2020-00839	<i>Pediococcus acidilactici</i> CNCM I-4622 for all animal species
EFSA-Q-2020-00840	AveMix 02 CS (endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and polygalacturonase) for piglets (suckling)
EFSA-Q-2020-00841	Vitamin E / all-rac- $\alpha$ -tocopheryl acetate for all animal species
EFSA-Q-2020-00843	CI-FER (ferric citrate chelate) for chickens for fattening, chickens reared for laying, turkeys reared for breeding, turkeys for fattening, all minor poultry species for rearing (up to slaughter or point of lay)
EFSA-Q-2020-00845	<i>Pediococcus pentosaceus</i> DSM 12834 for all animal species
EFSA-Q-2020-00846	<i>Lactococcus lactis</i> DSM 11037 for all animal species
EFSA-Q-2020-00847	<i>Lactobacillus acidophilus</i> D2/CSL (CECT 4529) for all poultry species and categories and all ornamental birds
EFSA-Q-2020-00848	Lanthan One (lanthanum carbonate octahydrate) for Cats

## 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-2020-00155	MSG (monosodium L-glutamate) produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80187 for all animal species	17/11/2020
EFSA-Q-2020-00174	Iron chelate of amino acids hydrate (Availa® Fe) for all animal species	19/01/2021
EFSA-Q-2020-00181	Manganese chelate of amino acids hydrate (Availa® Mn) for all animal species	19/01/2021
EFSA-Q-2020-00182	Copper chelate of amino acids hydrate (Availa® Cu) for all animal species	19/01/2021
EFSA-Q-2020-00212	Zinc chelate of amino acids hydrate (Availa® Zn) for all animal species	15/01/2021
EFSA-Q-2020-00584	Sodium nitrite (E 250) for pigs, poultry, bovines, ovines, goats, rabbits and horses	04/12/2020
EFSA-Q-2020-00585	Sodium nitrite (E 250) for pigs, poultry, bovines, ovines, goats, rabbits and horses	09/12/2020
EFSA-Q-2020-00600	Biosprint® ( <i>Saccharomyces cerevisiae</i> MUCL 39885) for all pigs (other than sows, suckling and weaned piglets) and other minor porcine species	08/01/2021
EFSA-Q-2020-00602	<i>Lactobacillus plantarum</i> DSM 21762 for all animal species	16/11/2020



EFSA-Q-Number	Subject	Valid on
EFSA-Q-2020-00604	L-Histidine monohydrochloride monohydrate for all animal species	20/11/2020
EFSA-Q-2020-00605	<i>Lactobacillus plantarum</i> DSM 12837 for all animal species	20/11/2020
EFSA-Q-2020-00614	<i>Lactobacillus plantarum</i> DSM 12836 for all animal species	20/11/2020
EFSA-Q-2020-00635	AveMix® 02CS (endo-1,4-beta-xylanase, endo-1,3 (4)-beta-glucanase and polygalacturonase) for piglets (weaned)	11/01/2021
EFSA-Q-2020-00636	L-lysine monohydrochloride and L-lysine sulphate for all animal species	08/12/2020
EFSA-Q-2020-00637	Vitamin B2 produced by <i>Bacillus subtilis</i> CGMCC 13326 for all animal species	18/01/2021
EFSA-Q-2020-00654	<i>Lactobacillus buchneri</i> DSM 16774 for all animal species	16/12/2020
EFSA-Q-2020-00691	<i>Lactobacillus brevis</i> DSM 12835 for all animal species	23/12/2020
EFSA-Q-2020-00692	<i>Lactobacillus rhamnosus</i> IMI 507023 for all animal species	07/01/2021
EFSA-Q-2020-00693	<i>Pediococcus pentosaceus</i> IMI 507024 for all animal species	07/01/2021
EFSA-Q-2020-00694	<i>Pediococcus pentosaceus</i> IMI 507025 for all animal species	07/01/2021
EFSA-Q-2020-00695	<i>Lactobacillus plantarum</i> IMI 507026 for all animal species	08/01/2021
EFSA-Q-2020-00696	<i>Lactobacillus plantarum</i> IMI 507027 for all animal species	07/01/2021
EFSA-Q-2020-00697	<i>Lactobacillus plantarum</i> IMI 507028 for all animal species	07/01/2021
EFSA-Q-2020-00706	<i>Lactobacillus rhamnosus</i> NCIMB 30121 for all animal species	12/01/2021
EFSA-Q-2020-00707	<i>Lactobacillus paracasei</i> DSM 16245 for all animal species	14/01/2021
EFSA-Q-2020-00769	<i>Lactobacillus buchneri</i> DSM 12856 for all animal species and categories	15/01/2021
EFSA-Q-2020-00837	Coxidin® (monensin sodium (carrier perlite, wheat bran)) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding	08/01/2021

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

This question was 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

#### a) Update on the implementation of Transparency Regulation

The Head of Regulated Products Department Guilhem De Seze and Claudia Paoletti from TS Unit provided an update on the implementation of the Transparency Regulation. This update addressed the EFSA's documents drafted/updated in a view of the Transparency regulation (Practical arrangements and guidance documents), the process on dossier submission as well as engagement, training and communication.

#### b) The Panel was informed on the feedback received from the observers attending the open session of the 150<sup>th</sup> plenary held in November.

### 7.3. European Commission

Not discussed.

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

#### a) Criteria for the assessment of efficacy for additives belonging to the functional group "hygiene condition enhancers".

The Panel discussed a proposal for the assessment of the efficacy of additives belonging to the functional group "hygiene condition enhancers" within the category of technological additives. The discussion will continue in one of the next plenaries.

## 9. Any other business

#### a) The Panel agreed to hold an extra plenary on 10 February 2021.





## Annex

### Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

With regards to this meeting, Dr. Ruud Woutersen declared the following interest: his signature appears in two reports on user safety for the item 5.5 Ronozyme<sup>®</sup> ProAct (serine protease EC 3.4.21.- produced by *Bacillus licheniformis* DSM 19670) for chickens for fattening (EFSA-Q-2019-00156). He explained that he was not the study director and he was not involved in the execution of the work; his signature represented the approval of the management. In accordance with EFSA's Policy on Independence<sup>[1]</sup> and the Decision of the Executive Director on Competing Interest Management<sup>[2]</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI). This results in the exclusion of the expert from the discussion, voting or other processing of the item 5.5 - Ronozyme<sup>®</sup> ProAct (serine protease EC 3.4.21.- produced by *Bacillus licheniformis* DSM 19670) for chickens for fattening (EFSA-Q-2019-00156).

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<sup>[1]</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>[2]</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)