FEED UNIT

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

## MINUTES OF THE 149th FEEDAP PLENARY MEETING

**Webconference, 30 September – 1 October 2020**

**(Agreed by written procedure on 9 October 2020)**

## 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**

  Almudena Rodriguez (DG SANTE)[1]

- **EFSA:**

  **Feed Unit**: Angelica Amaduzzi, Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Yolanda García Cazorla, 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.

- **Others:**

  Not applicable

## 1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received. The Chair welcomed Joana Revez as a new scientific officer in the FEED Unit.

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.

[1] Participated on 1 October only

European Food Safety Authority
Via Carlo Magno 1A – 43126 Parma, Italy
Tel. +39 0521 036 111
info@efsa.europa.eu | www.efsa.europa.eu

## 2. Adoption of agenda

The agenda was adopted after the addition of STENOROL® (Halofuginone hydrobromide) for chickens for fattening and turkeys (EFSA-Q-2012-00407) (see point 5.15).

## 3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], 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 148th FEEDAP Plenary meeting

The minutes of the 148th FEEDAP Plenary meeting were agreed by written procedure on 8 July 2020[4].

## 5. Scientific topics for discussion

### 5.1. Bonvital (*Enterococcus faecium* DSM 7134) for laying hens (EFSA-Q-2018-00419)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Bonvital (*Enterococcus faecium* DSM 7134) as a zootechnical additive for laying hens.

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

### 5.2. Nutrase P (6-phytase) for chickens for fattening, other poultry for fattening, reared for laying and ornamental birds (EFSA-Q-2019-00155)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Nutrase P (6-phytase) as a zootechnical additive for chickens for fattening, other poultry for fattening, 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.

2 Policy on Independence
3 Competing Interest Management
4 http://www.efsa.europa.eu/sites/default/files/event/2020/148th-plenary-meeting-feedap-panel-minutes.pdf

## 5.3. L-Lysine monohydrochloride/Concentrated liquid L-Lysine produced by fermentation with *Corynebacterium casei* KCCM80190 for all animal species (EFSA-Q-2019-00195)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-lysine monohydrochloride/Concentrated liquid L-Lysine produced by fermentation with *Corynebacterium casei* KCCM80190 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.

## 5.4. Update of Guidance on the renewal of feed additive authorizations (EFSA-Q-2019-00342)

This question refers to the self-task of the Panel on the revision of the guidance documents. This guidance document covers the renewal of feed additives authorisations.

The Panel was given an overview of the main changes introduced in the guidance document following the public consultation. However, given the time constrains it was not possible to have an in-depth discussion. The document will be tabled for adoption in the next plenary meeting.

## 5.5. Manganese chelate of hydroxy analogue of methionine (MINTREX® Mn) for all animal species (EFSA-Q-2019-00362)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of manganese chelate of hydroxy analogue of methionine as a nutritional 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.

## 5.6. Calsporin® (*Bacillus subtilis* C-3102, DSM 15544) for piglets (weaned) (EFSA-Q-2019-00370)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Calsporin® (*Bacillus velezensis* C-3102, DSM 15544, formerly *B. subtilis*) as a zootechnical additive for piglets (weaned).

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

## 5.7. *Bacillus subtilis* PB6 (*Bacillus subtilis* ATCC PTA-6737) for chickens for fattening, chickens reared for laying and minor poultry species (except for laying purpose), ornamental, sporting and game birds (EFSA-Q-2019-00410)

This question refers to the authorisation under Article 4, the modification of the conditions of the authorisation under Article 13 and the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Bacillus subtilis* PB6 (*Bacillus velezensis* ATCC PTA-6737, formerly *B. subtilis*) as a zootechnical additive for chickens for fattening, chickens reared for laying and minor poultry species (except for laying purpose), ornamental, sporting and game birds.

The draft opinion was discussed in the previous plenary, when the Panel identified the need to ask for supplementary information to the applicant. A revised draft opinion was

presented and the discussion focused mainly on the characterisation and safety of the additive. The Panel unanimously adopted the opinion.

### 5.8. L-Valine for all animal species (EFSA-Q-2019-00788)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-Valine 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. Correlink™ (*Bacillus subtilis* NRRL B-67257) for chickens for fattening, turkeys for fattening, chickens reared for laying, turkeys reared for breeding and minor poultry species (EFSA-Q-2019-00803)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Correlink™ (*Bacillus velezensis* NRRL B-67257, formerly *B. subtilis*) as a zootechnical additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor 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. Correlink™ (*Bacillus subtilis* NRRL B-67259) for chickens for fattening, turkeys for fattening, chickens reared for laying, turkeys reared for breeding and minor poultry species (EFSA-Q-2020-00006)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Correlink™ (*Bacillus velezensis* NRRL B-67259, formerly *B. subtilis*) as a zootechnical additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor poultry species.

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

### 5.11. L-Histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* K-12 KCCM 80212 for all animal species (EFSA-Q-2020-00189)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* K-12 KCCM 80212 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.

### 5.12. Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) for piglets (weaned) (EFSA-Q-2020-00313)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) as a zootechnical additive for piglets (weaned).

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

### 5.13. Pyridoxine hydrochloride for all animal species (EFSA-Q-2020-00325)

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

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

### 5.14. Chemically defined flavourings from Chemical Group 20 - aliphatic and aromatic mono- and di-thiols and mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups when used as flavourings: methanethiol [12.003] for all animal species and categories (EFSA-Q-2020-00459)

EFSA was requested to deliver an opinion on the safety and efficacy of methanethiol [12.003] (chemically defined flavourings from Chemical Group 20 - aliphatic and aromatic mono- and di-thiols and mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups when used as flavourings) as a sensory additive for all animal species and categories 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.

### 5.15. STENOROL® (Halofuginone hydrobromide) for chickens for fattening and turkeys (EFSA-Q-2012-00407)

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of STENOROL® (halofuginone hydrobromide) as a coccidiostat for chickens for fattening and turkeys.

The draft opinion was originally adopted in July 2020. However, after adoption it was identified that due to a clerical mistake, some information submitted by the applicant had not been made available to the Panel at the time of the adoption. Therefore, the Panel decided to withdraw the adoption of the opinion (before it was published). The missing information has been assessed and the updated opinion submitted to the panel for evaluation.

The draft opinion was discussed focusing mainly on the new information regarding efficacy. The Panel unanimously adopted the opinion which replaces the previously adopted one.

## 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-2020-00462 | Protural Granular, Protural Powder (sodium benzoate) for weaned piglets and other growing suidae |
| EFSA-Q-2020-00463 | Vitamin $B_6$ (pyridoxine hydrochloride) for all animal species |

| EFSA-Q-Number | Subject |
|---|---|
| EFSA-Q-2020-00495 | Selenised yeast *Saccharomyces cerevisiae* CNCM I-3060, inactivated (SEL-PLEX) for all animal species |
| EFSA-Q-2020-00496 | BA-KING® (*Bacillus amyloliquefaciens* TOA5001 (NITE BP-01844)) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, all minor avian species (including also sporting, ornamental and exotic birds) |
| EFSA-Q-2020-00498 | Taminizer D (dimethylglycine sodium salt) for chickens for fattening |
| EFSA-Q-2020-00499 | L-tryptophan produced by *Escherichia coli* KCCM 80210 (W008) for all animal species |
| EFSA-Q-2020-00502 | L-glutamic acid produced using strain NITE BP-01681, and its sodium salt (hydrate form) Monosodium glutamate monohydrate for all animal species |
| EFSA-Q-2020-00539 | Cycostat 66 G (robenidine hydrochloride) for rabbits for breeding and rabbits for fattening |
| EFSA-Q-2020-00546 | AVIMATRIX® Z (Preparation of benzoic acid, calcium formate and fumaric acid) for all avian species other than laying birds |
| EFSA-Q-2020-00597 | AVATEC® 150 G (lasalocid A sodium) for pheasants, guinea fowl, quails and partridges |
| EFSA-Q-2020-00598 | Blend of grape (*Vitis vinifera* L.) and wild blueberry (*Vaccinium angustifolium* A.) extracts (FLAMORE) |
| EFSA-Q-2020-00600 | Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) for all pigs (other than sows, suckling and weaned piglets) and other minor porcine species |
| EFSA-Q-2020-00614 | *Lactobacillus plantarum* DSM 12836 for all animal 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-2010-01462 | Sodium nitrite for dogs and cats | 10/07/2020 |
| EFSA-Q-2019-00664 | Carmine for dogs and cats | 24/08/2020 |
| EFSA-Q-2020-00279 | *Lactobacillus plantarum* DSM 26571 for all animal species | 22/07/2020 |
| EFSA-Q-2020-00282 | Sacox® (salinomycin sodium) for rabbits for fattening | 23/07/2020 |
| EFSA-Q-2020-00375 | L-valine for all animal species | 22/06/2020 |
| EFSA-Q-2020-00405 | Coxidin (monensin sodium, carrier perlite, calcium carbonate) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared from breeding | 05/08/2020 |
| EFSA-Q-2020-00463 | Vitamin $B_6$ (pyridoxine hydrochloride) for all animal species | 27/08/2020 |

| EFSA-Q-Number | Subject | Valid on |
|---|---|---|
| EFSA-Q-2020-00489 | Axtra® XB 201 TPT and Axtra® XB 201 L (endo-1,4-beta-xylanase EC 3.2.1.8 and endo-1,3(4)-beta-glucanase (E.C 3.2.1.6)) for All avian species, piglets (suckling and weaned piglets), pigs for fattening, lactating sows (including minor porcine species), minor growing porcine species | 08/09/2020 |
| EFSA-Q-2020-00495 | Selenised yeast *Saccharomyces cerevisiae* CNCM I-3060, inactivated (SEL-PLEX) for all animal species | 15/09/2020 |
| EFSA-Q-2020-00499 | L-tryptophan produced by *Escherichia coli* KCCM 80210 (W008) for all animal species | 15/09/2020 |

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-2020-00444 | Belfeed B MP/ML (endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* LMG S-15136) for pigs and sows, in order to have benefit in piglets |
| EFSA-Q-2020-00449 | *Verbascum thapsus* L. (great mullein tincture) for all animal species |
| EFSA-Q-2020-00459 | Chemically defined flavourings from Chemical Group 20 - aliphatic and aromatic mono- and di-thiols and mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups when used as flavourings: methanethiol [12.003] for all animal species and categories |

These questions 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 Request to EFSA and EMA for scientific and technical assistance in order to develop a common approach on risk assessment of residues from veterinary medicinal products and feed (EFSA-Q-2020-00536).
- The Panel was informed on the progress made in the context of the scientific opinion as regards specific maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed (EFSA-Q-2019-00221). The Panel was informed that the version of the document endorsed by the BIOHAZ Panel will be published in the coming weeks for public consultation. The main topic sent for public consultation is the methodology used to assess the development of antimicrobial resistance in microorganism in the target species exposed to the antimicrobials via feed.

### 7.3. European Commission

Not discussed.

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

a) A discussion took place regarding the assessment of the safety for the target animals of compounds for which genotoxicity has not been excluded in the framework of an application for authorisation of a feed additive.

b) Discussion took place on the use of enzymes obtained by fermentation in the manufacturing of other feed additives and the requirements for the assessment of such products. The Panel agreed that further discussion would be required and asked the WG on microbiology to present a formal position in the next plenary meeting.

c) The Panel was asked to provide input on the need to revise or update any of the guidance documents which are currently in use. Feedback will be collected and discussed in the next Plenary meeting.

## 9. Any other business

a) EFSA clarified that the expert appointed as working group chair may be invited to participate in the role of chair or member in a given working group meeting, based on EFSA's decision whether the agenda topics are sensitive and/or complex.

b) The Panel was informed about a series of errata identified in the opinions on "Safety and efficacy of copper chelates of lysine and glutamic acid as a feed additive for all animal species" (EFSA-Q-2018-00011) adopted on 15 May 2019, "Safety and efficacy of zinc chelates of lysine and glutamic acid as feed additive for all animal species" adopted on 1 July 2019, "Safety and efficacy of iron chelates of lysine and glutamic acid as feed additive for all animal species" adopted on 4 July 2019 and "Safety and efficacy of Manganese chelates of lysine and glutamic acid as feed additive for all animal species" adopted on 10 January 2020. These errata will be corrected.

c) The Panel was updated on the suspension of the authorisation of ethoxyquin as a feed additive.

d) The next plenary meeting (18-19 November) will have a session open to observers.