

# Scientific Panel on Additives and Products or Substances used in Animal Feed

## Minutes of the 122<sup>nd</sup> Plenary meeting

**Held on 18-20 October 2016, Parma (Italy)**

**(Agreed by written procedure on 24 October 2016)**

### Participants

#### ■ Panel Members

Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Secundino López Puente, Marta López-Alonso, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

#### ■ Hearing Experts:

Not Applicable

#### ■ European Commission and/or Member States representatives:

Not Applicable

#### ■ EFSA:

**FEED Unit:** Jaime Aguilera, Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Antonio Luís González, Lucilla Gregoretti, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini, Oriol Ribó, Manuela Tiramani and Maria Vittoria Vettori.

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

**BIOCONTAM Unit:** Pietro Stella<sup>2</sup>

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Pier Sandro Cocconcelli.

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<sup>1</sup> Present only on 18 AM for points 1 and 7.1.a

<sup>2</sup> Present only on 18 PM for point 8.a

The Chair welcomed also Guilhem De Seze, the Head of the Regulated Products (REPRO) department, who briefly introduced himself to the Panel.

The Chair also welcomed Antonio Luis González as a trainee in the FEED Unit.

## **2. Adoption of agenda**

The agenda was adopted without changes.

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>3</sup> and the Decision of the Executive Director on Declarations of Interest<sup>4</sup>, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Panel Members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

## **4. Agreement of the minutes of the 121<sup>st</sup> Plenary meeting held on 12-14 July 2016**

The minutes of the 121<sup>st</sup> Plenary meeting were agreed.<sup>5</sup>

## **5. Scientific outputs submitted for discussion and/or possible adoption<sup>6</sup>**

### **5.1 Chemically defined flavourings from Chemical Group 10 - Secondary aliphatic saturated or unsaturated alcohols/ ketones/ketals/esters with a second secondary or tertiary oxygenated functional group for all animal species and categories ([EFSA-Q-2010-00874](#))**

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of chemically defined flavourings from Chemical Group 10 as sensory additives for all animal species.

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>5</sup> <http://www.efsa.europa.eu/sites/default/files/event/160712b-m.pdf>

<sup>6</sup> During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.

The draft opinion was discussed. Discussion focussed mainly on the safety for the target species and the environment. The opinion was adopted.

**5.2 Chemically defined flavourings from Chemical Group 12 - Maltol derivatives and ketodioxane derivatives: maltol [07.014] for all animal species and categories ([EFSA-Q-2010-01033](#))**

The Chair of the working group (WG) presented the question and the draft opinion. This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of chemically defined flavourings from Chemical Group 12 as sensory additives for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the safety for the target species and the environment. The opinion was adopted.

**5.3 Tartrazine for dogs and cats, ornamental fish, grain-eating ornamental birds, small rodents ([EFSA-Q-2012-00661](#))**

The Chair of the WG presented the question and the draft opinion. This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of tartrazine as a sensory additive for dogs, cats, ornamental fish, grain-eating ornamental birds and small rodents.

The draft opinion was discussed. Discussion focussed mainly on the safety for the target species. The opinion was adopted.

**5.4 Feedlyve AXC (endo-1,4-beta-xylanase) for chickens for fattening ([EFSA-Q-2014-00228](#))**

A member of the WG presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Feedlyve AXC (endo-1,4-beta-xylanase) as a zootechnical additive for chickens for fattening.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, the safety for the target species, consumer and user and the efficacy. The opinion was adopted.

**5.5 Maxiban G160 (narasin and nicarbazin) for chickens for fattening ([EFSA-Q-2014-00666](#))**

The rapporteur presented the question and the draft opinion. This question refers modification of the terms of authorisation under Article 13 of Regulation (EC) No 1831/2003 of Maxiban G160 (narasin and nicarbazin) as a coccidiostat for chickens for fattening.

The draft opinion was discussed. The discussion focused mainly on the characterisation of the additive. The opinion was adopted.

#### **5.6 FUMzyme® (fumonisin esterase) for all avian species (EFSA-Q-2014-00900)**

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of FUMzyme® (fumonisin esterase) as a technological additive for all avian species.

The draft opinion was discussed. Discussion focussed mainly on the safety for the target species and the efficacy. The opinion was adopted.

#### **5.7 Feedlyve AGL (endo-1,4-beta-glucanase) for chickens for fattening (EFSA-Q-2014-00229)**

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Feedlyve AGL (endo-1,4-beta-glucanase) as a zootechnical additive for chickens for fattening.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, the safety for the target species, consumer and user and the efficacy. The opinion was adopted.

#### **5.8 Preparation of algae interspaced bentonite for all animal species (EFSA-Q-2015-00053)**

The Chair of the WG presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of a preparation of algae interspaced bentonite as a technological additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, the safety for the target species and the efficacy. The opinion was adopted.

#### **5.9 *Lactobacillus brevis* NCIMB 42149 for all animal species (EFSA-Q-2015-00280)**

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Lactobacillus brevis* as a technological additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive and the efficacy. The opinion was adopted.

### **5.10 B-Act (*Bacillus licheniformis* DSM 28710) for chickens for fattening, chickens reared for laying ([EFSA-Q-2015-00346](#))**

The rapporteur presented the question and the draft opinion. 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 chickens for fattening and chickens reared for laying.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive and the efficacy. The opinion was adopted.

### **5.11 3-phytase FLF 1000 for chickens for fattening and laying hens ([EFSA-Q-2015-00482](#))**

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of a 3-phytase as a zootechnical additive for chickens for fattening and laying hens.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, the safety for the target species and the user and the efficacy. The opinion was adopted.

### **5.12 Axtra® Phy 20000 TPT2 (6-phytase) for poultry and pig species ([EFSA-Q-2016-00075](#))**

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Axtra Phy 20000 TPT2 (6-phytase) as a zootechnical additive for poultry and porcine species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive. The opinion was adopted.

### **5.13 Alkosel (selenium enriched yeast, *Saccharomyces cerevisiae* NCYC R397) for all animal species ([EFSA-Q-2016-00088](#))**

The rapporteur presented the question and the draft opinion. This question refers to the modification of the current authorisation under Article 13 of Regulation (EC) No 1831/2003 of Alkosel (selenium enriched yeast, *Saccharomyces cerevisiae* NCYC R397) as a nutritional additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive and the safety for the user. The opinion was adopted.

#### **5.14 Natugrain® TS/TS L (endo-1,4-beta-xylanase and endo-1,4-beta-glucanase) for chickens reared for laying, minor poultry species for laying ([EFSA-Q-2016-00302](#))**

The Chair of the WG presented the question and the draft opinion. This question refers to the modification of the current authorisation under Article 13 of Regulation (EC) No 1831/2003 of Natugrain® TS/TS L (endo-1,4-beta-xylanase and endo-1,4-beta-glucanase) as a zootechnical additive for chickens reared for laying and minor poultry species for laying.

The draft opinion was discussed. Discussion focussed mainly on the safety for the target species and the efficacy. The opinion was adopted.

#### **5.15 Dry grape extract for all animal species (use in water) ([EFSA-Q-2016-00342](#))**

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of dry grape extract as a sensory additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the safety for the target species. The opinion was adopted.

### **6. New mandates**

#### **6.1 New applications under Regulation (EC) No 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:

<b>EFSA-Q-Number</b>	<b>Subject</b>
EFSA-Q-2016-00561	Bentonite for all animal species
EFSA-Q-2016-00568	<i>Lactococcus lactis</i> NCIMB 30160 for all animal species
EFSA-Q-2016-00574	L-lysine monohydrochloride and L-lysine sulphate from <i>Corynebacterium glutamicum</i> CCTCC M 2015595 for all animal species
EFSA-Q-2016-00580	<i>Lactobacillus spp.</i> CNCM I-4785 for all animal species
EFSA-Q-2016-00559	6-phytase weaned piglets, pigs for fattening, sows for reproduction, chickens for fattening, laying hens, turkeys for fattening and ducks for fattening
EFSA-Q-2016-00554	Zinc-L-selenomethionine 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-2016-00452	<i>Enterococcus faecium</i> DSM 7134 for piglets (weaned)	05/10/2016
EFSA-Q-2016-00450	<i>Enterococcus faecium</i> DSM 7134 for pigs for fattening	05/10/2016
EFSA-Q-2016-00455	Selenomethionine produced by <i>Saccharomyces cerevisiae</i> NCYC R397 for all animal species	24/08/2016
EFSA-Q-2016-00448	<i>Bacillus subtilis</i> DSM 29784 for chickens for fattening	05/10/2016

These applications were assigned to the respective working groups.

## 6.3 New questions under Regulation (EC) No 178/2002 since the previous meeting

EFSA-Q-Number	Subject
EFSA-Q-2016-00459	Natural mixture of dolomite plus magnesite and magnesium-phyllsilicates for all animal species
EFSA-Q-2016-00505	Vitamin B2 (riboflavin, produced with <i>Bacillus subtilis</i> CJKB0001) for all animal species
EFSA-Q-2016-00449	<i>Saccharomyces cerevisiae</i> CNCM I-1079 for weaned piglets and sows
EFSA-Q-2016-00551	L-tryptophan, technically pure for all animal species
EFSA-Q-2016-00570	L-tryptophan, technically pure, produced by <i>Escherichia coli</i> strains DSM 25084 and KCCM 11132P for all animal species
EFSA-Q-2016-00461	Cassia gum for dogs and cats

These questions were assigned to the respective working groups.

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

### 7.1 EFSA

- a) The Head of the FEED Unit (HoU) informed the Panel about the editorial published in the EFSA Journal regarding the review of authorship principles<sup>7</sup> and explained its practical application regarding the opinions of the Panel.
- b) The Panel was also informed that the pilot phase for the application of the draft guidance on uncertainty and the

<sup>7</sup> <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.e14091/epdf>

principles of Prometheus in a case study in the area of the FEEDAP Panel has started.

- c) The HoU provided information regarding the assessment of possible conflicts of interest derived from the reception by experts of prizes or awards.
- d) The HoU presented the new stakeholder engagement approach. The purpose of this activity is to engage with wider range of stakeholders, following the principles of authenticity, inclusiveness and balanced representation of views and interests. It is based on a system of registered stakeholders with a series of permanent and targeted mechanisms for stakeholder engagement. It will consist in targeted and permanent platforms, according to the needs of the engagement.

## 7.2 Working groups

- a) The Chair of the WG on guidance update informed the Panel on the progress in the work and the next steps.
- b) The Chair of the WG on colouring agents updated the Panel on the status of the assessment of titanium dioxide used as a feed additive for all animal species. The WG made a proposal for the next steps which was agreed by the Panel.

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

- a) **Request for a joint EFSA and EMA scientific opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union and the resulting impacts on food safety (EFSA-Q-2015-00216)<sup>8</sup>**

A staff member presented the draft opinion. EFSA has been requested to produce a joint opinion with EMA on the measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety. The mandate was assigned to the BIOHAZ Panel. The FEEDAP Panel has been requested to endorse chapter "4.4 Alternative methods" of the draft opinion. The concerned chapter was discussed. The Panel endorsed the chapter with the proposal of some minor changes.

- b) The Panel was informed of comments submitted by individual experts to the terms of reference of the Scientific Committee's self-tasking mandate on harmonisation of risk assessment methodologies for human health and ecological risk assessment

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<sup>8</sup> The expert Maryline Kouba declared that she is participating in a similar exercise at ANSES and therefore abstained from the participation in the discussion and the endorsement of this item.

of combined exposure to multiple chemicals (EFSA-Q2016-00307)

## 9. Any other business

- a) Following the final screening of the ADoI, Giovanna Azimonti will be the Chair of the WG on updating the guidance for environmental risk assessment of feed additives instead of Boris Kolar (eligible for membership only).
- b) The Panel was informed about errata identified in the opinion on BIOSTRONG<sup>®</sup> 510 as feed additive (essential oil of thyme and star anise) for chickens and minor avian species for fattening and rearing to point of lay (EFSA-Q-2011-01152) adopted on 4 December 2015 which were corrected.