

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

## Minutes of the 123<sup>rd</sup> Plenary meeting

**Held on 6-8 December 2016, Parma (Italy)**

**(Agreed by written procedure on 15 December 2016)**

### Participants

#### ■ Panel Members

Gabriele Aquilina, Giovanna Azimonti,<sup>1</sup> Vasileios Bampidis, Maria de Lourdes Bastos, Andrew Chesson, Pier Sandro Cocconcetti, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Marta López Alonso, Secundino López Puente, Alberto Mantovani,<sup>2</sup> 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:

Marta Ponghellini (DG SANTE)

#### ■ EFSA:

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

**RISCOM Unit:** Arthur Healy<sup>3</sup>

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Georges Bories.

The Chair also welcomed Agnese Balzani as a trainee in the Feed unit.

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<sup>1</sup> Present on 6 and 7 December

<sup>2</sup> Present on 7 and 8 December

<sup>3</sup> Present only on 7 December for point 9.a

## **2. Adoption of agenda**

The agenda was adopted with the deletion of the items “Vitamin D<sub>3</sub> addition to feedingstuffs for fish (EFSA-Q-2014-00604)” and “*Bacillus subtilis* PB6 (*Bacillus subtilis* ATCC PTA-6737) for sows, in order to have benefits in piglets (EFSA-Q-2014-00587)”.

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

In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes<sup>4</sup> and the Decision of the Executive Director on Declarations of Interest<sup>5</sup>, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Panel Members invited for the present meeting. For further details on the outcome of the screening of the ADoI or the SDoI, please refer to the Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interests were declared.

## **4. Agreement of the minutes of the 122<sup>nd</sup> Plenary meeting held on 18-20 October 2016**

The minutes of the 122<sup>nd</sup> Plenary meeting held on 18-20 October 2016 were agreed by written procedure on 24 October 2016.<sup>6</sup>

## **5. Scientific outputs submitted for discussion and/or possible adoption**

### **5.1 Chemically defined flavourings from Chemical Group 24 - Pyrazine derivatives ([EFSA-Q-2010-01032](#))**

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 24 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.

### **5.2 Chemically defined flavourings from Chemical Group 22 - Aryl-substituted primary alcohol/aldehyde/acid/ester**

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

<sup>5</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>6</sup> <http://www.efsa.europa.eu/sites/default/files/event/161018a-m.pdf>

**/acetal derivatives, including unsaturated ones ([EFSA-Q-2010-01042](#))**

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 22 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 Sacox (salinomycin sodium) for chickens for fattening and chickens reared for laying ([EFSA-Q-2012-00994](#), [EFSA-Q-2013-00706](#), [EFSA-Q-2013-00998](#))**

The Chair of the WG presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of Sacox (salinomycin sodium) as a coccidiostat for chickens for fattening and chickens reared for laying.

The draft opinion was discussed. Discussion focussed mainly on the safety for the target species, the consumer and the environment as well as the efficacy. The opinion was adopted.

**5.4 Hemicell<sup>®</sup> HT (endo-1,4-beta-mannanase) for piglets (weaned), pigs for fattening, minor porcine species, chickens for fattening, chickens reared for laying, minor poultry species, turkeys reared for breeding, turkeys for fattening ([EFSA-Q-2014-00115](#))**

The Chair of the WG presented the question and the draft opinion. This question refers to authorisation under Article 4 of Regulation (EC) No 1831/2003 of Hemicell<sup>®</sup> HT (endo-1,4-beta-mannanase) as a zootechnical additive for piglets (weaned), pigs for fattening, minor porcine species, chickens for fattening, chickens reared for laying, minor poultry species, turkeys reared for breeding and turkeys for fattening.

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

**5.5 Iron dextran for piglets ([EFSA-Q-2014-00592](#))**

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 Iron dextran as a nutritional additive for piglets.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive, safety for the target species and efficacy. The Panel asked the WG to address several comments that were raised in the discussion and to present an updated draft to the next Plenary meeting.

**5.6 BIOMIN BBSH 797® (DSM 11798; Genus nov. species nov) for all avian species ([EFSA-Q-2015-00145](#))**

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of the bacterium DSM 11798 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 Levucell SB20/SB10 ME/SB10 ME Titan (*Saccharomyces cerevisiae* CNCM I-1079) for chickens for fattening and minor poultry species ([EFSA-Q-2015-00287](#))**

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 Levucell (*Saccharomyces cerevisiae*) as a zootechnical additive for chickens for fattening and minor poultry species.

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

**5.8 *Lactobacillus rhamnosus* DSM 29226 for all animal species ([EFSA-Q-2015-00626](#))**

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 rhamnosus* DSM 29226 as a technological additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the efficacy. The opinion was adopted.

**5.9 *Lactobacillus plantarum* DSM 29024 for all animal species ([EFSA-Q-2015-00627](#))**

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 plantarum* DSM 29024 as a technological additive for all animal species.

The draft opinion was discussed. Discussion focussed mainly on the efficacy. The opinion was adopted.

#### **5.10 Hostazym® X (endo-1,4-beta-xylanase) for chickens reared for laying and minor poultry species reared for laying ([EFSA-Q-2015-00834](#))**

Not discussed due to lack of time.

#### **5.11 Vevovitall (Benzoic acid) for weaned piglets and piglets for fattening ([EFSA-Q-2016-00017](#))**

Not discussed due to lack of time

### **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:

EFSA-Q-Number	Subject
EFSA-Q-2016-00648	ECONASE® XT (endo-1,4-beta-xylanase) for pigs for fattening
EFSA-Q-2016-00669	<i>Lactobacillus buchneri</i> NRRL B-50733 for all animal species
EFSA-Q-2016-00668	GalliPro® ( <i>Bacillus subtilis</i> DSM 17299) for chickens for fattening
EFSA-Q-2016-00713	<i>Lactobacillus animalis</i> LA51 (ATCC PTA-6750) for all animal species
EFSA-Q-2016-00711	Biacton ( <i>Lactobacillus farciminis</i> CNCM MA67/4R) for laying hens, chickens and turkeys for fattening
EFSA-Q-2016-00712	Biacton ( <i>Lactobacillus farciminis</i> CNCM MA67/4R) for piglets (weaned)

#### **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-2016-00561	Bentonite for all animal species	24/10/2016

EFSA-Q-2016-00559	PHYZYME® XP 5000 G, PHYZYME® XP 5000 L (6-phytase) for weaned piglets, pigs for fattening, sows for reproduction, chickens for fattening, laying hens, turkeys for fattening and ducks for fattening	24/10/2016
EFSA-Q-2016-00554	Zinc-L-selenomethionine (Avalia Se) for all animal species	24/10/2016

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-2016-00645	Lactic acid and calcium lactate for all animal species
EFSA-Q-2016-00646	<i>Bacillus amyloliquefaciens</i> NCIMB 30229 for all animal species
EFSA-Q-2016-00644	Cassia gum for cats and dogs

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 draft opinion of the Scientific Committee on Motivations and criteria to consider updating EFSA scientific assessments.
- b) The HoU also informed the Panel on the procedures in EFSA regarding how to deal with forgery and false data on documents in application dossiers.
- c) The HoU updated the Panel on the results of the customer feedback exercise with DG SANTE.
- d) The Panel was also informed that the calendar for open plenaries for 2017 has been agreed. The FEEDAP Panel will hold an open plenary in September 2017.
- e) The Panel was also informed on the adoption by the BIOHAZ Panel of the 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).

### 7.2 Scientific Committee

- a) One Vice-Chair of the Panel reported on the main topics discussed during the last plenary meeting of the Scientific Committee. This was a meeting open to observers. The draft guidance documents on weight of evidence approach and on biological relevance were discussed.

### 7.3 Working Groups

- a) The Chair of the WG on Genetically Modified Microorganisms informed the Panel regarding the progress of the work in the Guidance document for the risk assessment of additives produced with genetically modified microorganisms.
- b) The Chair of the WG on Guidance Update on Safety of Feed Additives for the Environment gave an overview of the progress in the work to update the guidance for the environmental risk assessment and the work plan for the next months. The Panel supported the work done so far and added comments on new aspects that could be considered in the future steps.
- c) The Chair of the WG on Guidance update reported on the technical hearing that took place on 16-17 November with hearing experts from industry associations regarding the update of the guidance documents. In that meeting hearing experts were invited to provide their views on aspects related to the assessment of the safety for the target species and the efficacy of feed additives.

The Panel was also informed on the progress made in the update of the guidance document regarding safety for the target species.
- d) The Chair of the WG on Feed flavourings thanked the members of the current and past WG and the Feed unit staff Paola Manini and Lucilla Gregoretti, for the effort in finalising the opinions on chemically defined flavourings.

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

Not discussed

## 9. Any other business

- a) Discussion took place regarding the authorship principles for scientific outputs. A. Healy (EFSA Journal) presented some slides on the recently implemented authorship rules in EFSA. The Panel members added comments to those already collected during the last Plenary and sent to Arthur by the HoU.
- b) The Panel was consulted on an erratum identified in the opinion on Safety and efficacy of manganese compounds (E5) as feed additives for all animal species (EFSA-Q-2012-00437) adopted on 27 January 2016. The Panel agreed on the correction proposed.

## Annex

### **Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)**

In the ADoI or in the SDoI filled for the present meeting Dr Baltasar Mayo declared the following interests: he had a past research activity with the applicant of the products *Lactobacillus rhamnosus* DSM 29226 for all animal species (EFSA-Q-2015-00626) and *Lactobacillus plantarum* DSM 29024 for all animal species (EFSA-Q-2015-00627) (items 5.8 and 5.9). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>7</sup> and the Decision of the Executive Director on Declarations of Interest<sup>8</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.

This results in exclusion of the expert from any discussion, voting or other processing of the items 5.8 and 5.9 by the concerned scientific group.

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<sup>7</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>8</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>