

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

### Minutes of the 118<sup>th</sup> Plenary meeting

Held on 8-9 March 2016, Parma

(Agreed on 19 April 2016)

#### Participants

- **Panel Members:**

Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli,<sup>1</sup> Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Secundino López Puente, Marta López-Alonso, Alberto Mantovani,<sup>2</sup> Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa,<sup>3</sup> Robert John Wallace and Pieter Wester.

- **Hearing Experts:**

Not applicable

- **European Commission and/or Member States representatives:**

Not applicable

- **EFSA:**

**FEED Unit:** Manuela Tiramani, Jaume Galobart, Jaime Aguilera, Lucilla Gregoretta, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini, Oriol Ribó, Jordi Tarrés-Call and Maria Vittoria Vettori.

**Legal Unit:** Citlali Pintado<sup>4</sup>

- **Others:**

Not applicable

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<sup>1</sup> Not present on 9 March AM.

<sup>2</sup> Not present on 9 March AM.

<sup>3</sup> Not present on 9 March PM.

<sup>4</sup> Present only on 9 March for item 7.1.c.

## 1. Welcome and apologies for absence

The Chair welcomed all participants. No apologies were received.

## 2. Adoption of agenda

The agenda was adopted after deletion of “Diarr-Stop S Plus (Na<sub>2</sub>EDTA, *Castanea sativa*, thyme oil, oregano oil) for pigs for fattening (EFSA-Q-2011-00060)”.

## 3. Declarations of Interest of Scientific Panel members

In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest,<sup>6</sup> EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group 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 117<sup>th</sup> Plenary meeting held on 26-28 January 2016

The minutes of the 117<sup>th</sup> Plenary meeting were reviewed and agreed.<sup>7</sup>

## 5. Scientific topics for discussion and/or possible adoption<sup>8,9</sup>

### 5.1. Chemically defined flavourings from Chemical Group 08 - Secondary alicyclic saturated and unsaturated alcohols/ketones/ketals/esters with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols ([EFSA-Q-2010-01181](http://www.efsa.europa.eu/en/keydocs/docs/independencerule2014.pdf))

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of chemically defined flavourings from Chemical Group 08 as sensory additives for all animal species.

The draft opinion was discussed. The Panel concluded that the additives are safe for the target species, the consumer and expressed

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

<sup>6</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>7</sup> <http://www.efsa.europa.eu/sites/default/files/event/160126a-m.pdf>

<sup>8</sup> During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.

<sup>9</sup> For a detailed outcome of the assessment, please refer to the respective opinions published on the EFSA website.

concerns for the safety for the users and the environment. The Panel also concluded that no demonstration of efficacy was necessary.

The opinion was adopted.

## **5.2. Polyoxyethylene (20) sorbitan monooleate for all animal species ([EFSA-Q-2010-01222](#))**

The Chair of the Working group (WG) presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of polyoxyethylene (20) sorbitan monooleate as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species and consumers and is efficacious as an emulsifier. Concerns for users are limited to sensitised people. The Panel could not conclude on the safety of the additive for the environment.

The opinion was adopted.<sup>10</sup>

## **5.3. Ethyl ester of beta-apo-8'-carotenoic acid for poultry for fattening and poultry for laying ([EFSA-Q-2010-01300](#))**

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of ethyl ester of beta-apo-8'-carotenoic acid as a sensory additive for poultry for fattening and for laying.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species at 8 mg/kg feed for laying hens and minor laying species and 15 mg/kg for chickens for fattening and minor poultry species for fattening, but could not conclude on the safety at 80 mg/kg feed. The additive is also safe for the consumers provided that the use in feed for laying hens is reduced to 5 mg/kg feed. The Panel proposed setting maximum residue limits to ensure consumer safety. The additive is safe for the environment and for users following dermal/eye exposure, but no conclusion could be reached on the risk by inhalation. The Panel also concluded that the additive is efficacious.

The opinion was adopted.<sup>11</sup>

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<sup>10</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/4443>

<sup>11</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/4439>

**5.4. Kelforce (L-glutamic acid, N,N-diacetic acid, tetrasodium salt (GLDA-Na<sub>4</sub>)) for chickens for fattening ([EFSA-Q-2013-00434](#))**

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 Kelforce (L-glutamic acid, N,N-diacetic acid, tetrasodium salt (GLDA-Na<sub>4</sub>)) as a zootechnical additive for chickens for fattening.

The draft opinion was discussed. The Panel identified the need to request additional information to the applicant in order to reach a conclusion on the safety and efficacy of this additive.

The applicant will be requested to provide additional information.

**5.5. Chemically defined flavourings from Flavouring Group 29 - 2,4,5-trimethylthiazole, 2-acetylthiazole, 2-ethyl-4-methylthiazole, 2-isobutylthiazole, 2-isopropyl-4-methylthiazole, 4,5-dihydrothiophen-3(2H)-one, 5,6-dihydro-2,4,6-trans(2-methylpropyl)4H-1,3,5-dithiazine, 4-methyl-5-vinylthiazole, 5-(2-hydroxyethyl)-4-methylthiazole, benzothiazole and thiamine hydrochloride for all animal species and categories ([EFSA-Q-2013-00569](#))**

The Chair of the WG presented the question and the draft opinion. This question refers to the authorisation under Article 4 and the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of chemically defined flavourings from Chemical Group 29 as sensory additives for all animal species.

The draft opinion was discussed. The Panel concluded that the additives are safe for the target species, the consumer and the environment but expressed concerns for the safety for the users. The Panel also concluded that no demonstration of efficacy was necessary.

The opinion was adopted.

**5.6. Sodium selenite for all animal species ([EFSA-Q-2014-00507](#))**

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 sodium selenite as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species; it is safe for the consumers and the environment provided the maximum selenium contents

authorised in feed are respected. Concerns arose for users. The Panel also concluded that the additive is an efficacious source of selenium.

The opinion was adopted.<sup>12</sup>

### **5.7. L-tryptophan technically pure, produced by *Escherichia coli* CGMCC 7.59 for all animal species ([EFSA-Q-2015-00557](#))**

The Chair of the WG presented the question and the draft opinion. EFSA has been asked to deliver an opinion on the safety of L-tryptophan produced by *Escherichia coli* CGMCC 7.59 when used as a nutritional additive for all animal species based on the supplementary information provided by the applicant.

The draft opinion was discussed. The Panel reiterated the concerns expressed in the previous opinion with regards to the use of unprotected tryptophan in ruminants and the use of this amino acid in water for drinking. The Panel also concluded that the endotoxin activity of the final product does not represent a health risk for the user upon inhalation but the additive should be considered a potential dermal sensitiser.

The opinion was adopted.

### **5.8. LANCER (Lanthanide-citrate) for weaned piglets ([EFSA-Q-2015-00718](#))**

The Chair of the WG presented the question and the draft opinion. EFSA has been asked to deliver an opinion on the safety of Lancer (lanthanide citrate) when used as a zootechnical additive for weaned piglets based on the supplementary information provided by the applicant.

The draft opinion was discussed. The Panel identified some issues which required further clarification and asked the WG to submit a new draft to the next plenary meeting.

## **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, who accepted it:

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<sup>12</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/4442>

EFSA-Q-Number	Subject
EFSA-Q-2016-00088	Selenium enriched yeast ( <i>Saccharomyces cerevisiae</i> NCYC R397) (Alkosel 3000) for all animal species
EFSA-Q-2016-00112	Natural essential oil from <i>Origanum vulgare</i> L. ssp. <i>hirtum</i> var. Vulkan (DOS 00001) for all animal species
EFSA-Q-2016-00179	Beltherm MP and Beltherm BL (endo-1,4-beta-xylanase (IUB: EC 3.2.1.8)) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor poultry species, turkeys for breeding purposes

## 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-2015-00766	Sodium molybdate, dihydrate for all animal species	25/01/2016
EFSA-Q-2015-00834	Hostazym (endo-1,4-beta xylanase) for chickens reared for laying, minor poultry species reared for laying	02/02/2016
EFSA-Q-2016-00075	AXTRA <sup>®</sup> PHY 20000 TPT (20000 FTU/g 6-phytase) for piglets (weaned), sows for reproduction, pigs for fattening, minor porcine species, chickens for fattening, chickens reared for laying, laying hens, turkeys for breeding purposes, turkeys for fattening, turkeys reared for breeding, minor poultry species	01/03/2016
EFSA-Q-2016-00078	Phyllite, natural mixture of minerals of metamorphic origin. Minimum content of phyllo-, and alumo-/alumohydrosilicates like muscovite, illite, chlorite and talc $\geq$ 40% (by mass) for all animal species	01/03/2016

These applications were assigned to the respective working groups.

## 6.3. Questions under Regulation (EC) No 178/2002 since the previous meeting

EFSA-Q-Number	Subject
EFSA-Q-2016-00130	<i>Saccharomyces cerevisiae</i> NBRC 0203, <i>Lactobacillus plantarum</i> NBRC 3070 and <i>Lactobacillus casei</i> NBRC 3425 (EM-silage)

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

### 7.1. Feedback from EFSA

- a) The Panel was informed on the outcome of a post-adoption teleconference held with one applicant following the adoption of a negative opinion.

- b) The Panel was also informed about the meeting of the Standing Committee on Plants, Animals, Food and Feed, section Animal Nutrition with regards the revision of Regulation (EC) No 429/2008. EFSA was invited to present the work on the update of the guidance documents and on the revision of the above regulation.
- c) Citlali Pintado, from the Legal and Regulatory Unit presented recent case law developments, in particular a case relating to a request for draft documents submitted under Regulation (EC) No 1049/2001 on public access to documents, and its impact on EFSA's work. The judgement concerned the link between names of experts and their comments. Experts were informed that that EFSA expects to receive more similar requests for access to documents focussing on names linked to comments and that if this should be the case EFSA will engage with them on such requests.

## **7.2. Feedback from the Scientific Committee**

- a) The Head of Unit and the Chair of the Panel reported on the last meeting of the Scientific Committee, namely on the discussions on the application of the guidance on uncertainty.

## **7.3. Feedback from the Scientific Panels**

- a) A member from the Panel reported on the progress in the work of the WG on Reduction of the need to use antimicrobials from the BIOHAZ Panel.

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

The Chair of the WG of Feed Flavourings proposed the plenary to discuss the approach to assess the safety of smoke flavourings when used in feed for cats and dogs.

## **9. Any other business**

- a) The plenary meeting of 12-14 July will have a session open to observers. After the plenary meeting, there will be an info session. Information regarding the organisation and the topics that will be discussed at both meetings will be published on the website.
- b) The Panel was informed that the following experts were nominated as Vice-Chairs of the respective Standing WGs: Baltasar Mayo of the WG on Genetically modified microorganisms, Gerhard Flachowsky of the WG on Amino acids and vitamins and Georges Bories of the WG on Colourings.

## Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS)

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

### JOINT SESSION

10 March 2016, Parma

### Participants

- **ANS Panel Members:**

Fernando Aguilar, Riccardo Crebelli,<sup>13</sup> Alessandro Di Domenico, Birgit Dusemund, Maria José Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Claude Lambré, Jean-Charles Leblanc, Peter Moldeus, Alicja Mortensen, Pasquale Mosesso, Agneta Oskarsson, Dominique Parent-Massin, Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf Antonius Woutersen, Matthew Wright, Maged Younes

- **FEEDAP Panel Members:**

Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, 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:**

Wim Debeuckelaere (DG SANTE)

- **EFSA:**

**FEED Unit:** Manuela Tiramani, Jaume Galobart, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini and Maria Vittoria Vettori.

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<sup>13</sup> Via teleconference.

**Food ingredients and Packaging (FIP) Unit:** Dario Battacchi, Anna Christodoulidou, Paolo Colombo, Juho Lemmetyinen, Federica Lodi, Ana Maria Rincón, Claudia Roncancio Peña, Camilla Smeraldi, Alexandra Tard, Stavroula Tasiopoulou

- **Others:**

Not applicable

## **1. Welcome and apologies for absence**

The Chairs of the Panels welcomed all the participants to the joint session of the ANS and FEEDAP Panels. Apologies were received from Peter Moldeus (ANS Panel).

## **2. Adoption of the agenda**

The agenda was adopted without changes.

## **3. Introduction of Panel members**

The members of the two Panels briefly introduced themselves giving a short summary of their background and areas of expertise.

## **4. Legislative background and relevant guidance documents**

Members of the FIP and FEED units gave an overview of the legislative framework under which each Panel operates as well as of the different guidance documents.

## **5. Work plan and common areas of work**

The Chairs of the WGs, which share common areas between the two Panels, presented the work plan for the next years, with emphasis on those substances which will be assessed for both food and feed use.

## **6. Lessons learnt from the past**

Members of the FIP and FEED Units explained the past and current activities which are in place to address cross-cutting issues between the two Panels.

## **7. Open discussion: Future collaboration**

Some proposals to further strengthen cooperation between the two Panels were preliminarily discussed.

## **8. Any other business**

The chairs closed the meeting thanking all the participants for the interesting discussion and expressing the willingness to have another joint meeting in the future.