

FEED UNIT

**SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED
(FEEDAP)**

**Minutes of the 91st Plenary Meeting
Held on 13-15 November 2012, Barcelona**

(Agreed on 11 December 2012)

Participants

- **Panel Members**

Alex Bach, Vasileios Bampidis, Maria De Lourdes Bastos, Gerhard Flachowsky, Josep Gasà-Gasó, Mikolaj Gralak, Christer Hogstrand, Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Derek Renshaw, Guido Rychen,¹ Maria Saarela, Kristen Sejrsen, Patrick van Beelen, John Wallace and Johannes Westendorf.²

- **Hearing Experts**

N/A

- **European Commission**

N/A

- **EFSA**

- **Feed Unit:** Claudia Roncancio-Peña, Jaume Galobart, Gloria López-Gálvez, Paola Manini and Lucilla Gregoretti.
- **Other EFSA Directorates/Units:** N/A

1. Welcome and apologies for absence

The Vice-Chair welcomed the participants.

Apologies were received from Gabriele Aquilina.

2. Adoption of agenda

The agenda was adopted after the deletion of the items concerning “Calcium iodate anhydrous and potassium iodide for all animal species” (EFSA-Q-2011-00744) and “Calcium iodate anhydrous and potassium iodide for all animal species” (EFSA-Q-2011-00746).

3. Declarations of interest

In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests and the Decision of the Executive Director implementing this Policy, EFSA screened the Annual Declaration of Interests (ADoI) and the

¹ Present only on 14 November.

² Present via webconference on 14 November AM.

Specific Declaration of Interests (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the ADoI and SDoI please refer to the Annex.

4. Agreement of the minutes of the 90th Plenary meeting held on 16-18 October 2012, Parma

The minutes of the 90th Plenary meeting were reviewed and agreed.³

5. Scientific outputs submitted for discussion and possible adoption

5.1. Prostora Max (*Bifidobacterium animalis* subsp. *animalis* NCIMB 41617) for dogs (EFSA-Q-2009-00817)

The Chair of the Working Group presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the product Prostora Max (*Bifidobacterium animalis* ssp. *animalis* NCIMB 41617) as a zootechnical additive for dogs.

The draft opinion was discussed. The Panel concluded that the *B. animalis* ssp. *animalis* strain is resistant to the antibiotic clindamycin, and thus, the qualified presumption of safety approach cannot be applied. The genetic basis of the resistance to clindamycin was not established, and therefore, the extent of the risk of horizontal gene transfer to other bacteria in the food chain and in the environment cannot be established. The product is in a tablet form so exposure to mucous membranes and the respiratory system of users is unlikely. Some limited skin exposure might occur. Taking into consideration the results of the three studies assessed, the FEEDAP Panel cannot conclude on the efficacy of Prostora Max for dogs.

The opinion was adopted.⁴

5.2. Biomin C3 (*Enterococcus faecium*, *Bifidobacterium animalis* ssp. *animalis* and *Lactobacillus salivarius* ssp. *salivarius*) for chickens for fattening (EFSA-Q-2009-00823)

The Chair of the Working Group presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the product Biomin C3 (*Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913) as a zootechnical additive for dogs.

The draft opinion was discussed. The Panel concluded that Biomin C3 is safe for the target species at doses up to 1×10^9 CFU/kg of complete feedingstuffs, for the consumers and for the environment. The additive is not irritant to skin or eyes and is not a skin sensitiser but should be treated as a potential respiratory sensitiser, due to its proteinaceous nature. In four studies made with chickens for fattening, Biomin C3 showed the potential to improve the performance of birds at the minimum dose of 1×10^8 CFU/kg of complete feedingstuffs. The three strains are compatible with robenidine hydrochloride, maduramycin ammonium and diclazuril but not with monensin sodium and lasalocid A sodium.

³ <http://www.efsa.europa.eu/en/events/event/121016-m.pdf>

⁴ <http://www.efsa.europa.eu/en/efsajournal/pub/2964.htm>

The opinion was adopted.⁵

5.3. Chemically defined flavourings from Chemical Group 01 - Straight-chain primary aliphatic alcohols/aldehydes/acids, acetals and esters for all animal species (EFSA-Q-2010-00702)

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the chemically defined flavourings from Chemical Group 01 as sensory additives for all animal species.

The draft opinion was discussed. The Panel asked the working group to reconsider the assessment of the data provided on the safety for the target species.

5.4. Chemically defined flavourings from Flavouring Group 06 - Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols. Esters may contain any acid component: 13 substances for all animal species and categories (EFSA-Q-2010-00873)

The Chair of the Working Group presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the chemically defined flavourings from Chemical Group 06 as sensory additives for all animal species.

The draft opinion was discussed. The Panel concluded that nerolidol, 2-methyl-1-phenylpropan-2-ol and 2-(4-methylphenyl)propan-2-ol are safe at 1 mg/kg complete feed for pigs and poultry and 1.5 mg/kg complete feed for all other species. Linalool is safe for salmonids, veal calves, cattle for fattening and pets (excluding cats) at the high use level proposed by the applicant. The other compounds are safe for all animal species at the highest use level proposed by the applicant. These compounds are safe for the consumer when used up to the highest safe level in feedingstuffs for all animal species. These compounds should be considered as irritants to skin, eyes and respiratory tract, and as skin sensitisers. All of the compounds are safe for the soil compartment but not all of the compounds were considered safe for the aquatic compartment. They are considered efficacious when used in feed.

The opinion was adopted.⁶

5.5. Chemically defined flavourings from Flavouring Group 16 - Aliphatic and alicyclic ethers for all animal species and categories (EFSA-Q-2010-00989)

The Chair of the Working Group presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the chemically defined flavourings from Chemical Group 16 as sensory additives for all animal species.

The draft opinion was discussed. The Panel was unable to perform an assessment of 1,5,5,9-tetramethyl-13-oxatricyclo[8.3.0.0.(4.9)]tridecane and theaspirane because of issues related to the purity of the compounds. The Panel concluded that 2-(2-methylprop-1-enyl)-4-methyltetrahydropyran is safe at a maximum of 0.3 mg/kg complete feed for cattle, salmonids and non food-producing animals and of 0.5 mg/kg

⁵ <http://www.efsa.europa.eu/en/efsajournal/pub/2965.htm>

⁶ <http://www.efsa.europa.eu/en/efsajournal/pub/2966.htm>

complete feed for pigs and poultry. These compounds are safe for the consumer and the environment when used up to the highest safe level in feedingstuffs for all animal species. These compounds should be considered as irritants to skin, eyes and respiratory tract and as skin sensitisers. They are considered efficacious when used in feed.

The opinion was adopted.⁷

5.6. Methionine-zinc technically pure for all animal species (EFSA-Q-2010-01315)

The rapporteurs presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation of a new use under Article 4 of Regulation (EC) No 1831/2003 of methionine-zinc technically pure as a nutritional additive for all animal species.

The draft opinion was discussed. The discussion was not finalised and therefore the opinion will be submitted to the next Plenary meeting for discussion and possible adoption.

5.7. *Bacillus amyloliquefaciens* (NCIMB 30229) as a silage feed additive for all species (EFSA-Q-2011-00389)

Not discussed due to lack of time

5.8. Cupric sulphate pentahydrate for all animal species (EFSA-Q-2011-00743)

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 cupric sulphate pentahydrate as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for all animal species and the consumer. The additive is an eye irritant and may induce allergic dermatitis in sensitive patients, which might be exacerbated by the contamination by nickel; users may be exposed to hazardous copper concentrations by inhalation. Potential risks to soil organisms have been identified after application of piglet manure. There might be a potential concern related to sediment contamination. The use of copper compounds in aquaculture is not expected to pose a risk. Final conclusions would need further model validation and refinement to the assessment of copper-based additives in livestock. Copper sulphate pentahydrate is efficacious in meeting animals' requirements.

The MRLs for copper in foods of animal origin established by EU pesticides legislation are not consistent with legal practices in animal nutrition. Since copper is an essential micronutrient, the FEEDAP Panel is not in favour of establishing MRLs for animal products, unless there is a clear consumer safety issue; if MRLs are to be maintained, the Panel proposed amended values.

The limited database available on the influence of copper to the development of antibiotic resistance in gut and soil bacteria indicates that high copper concentrations in the microbial environment increase the number of copper-resistant bacteria and copper resistance seems to be correlated with a more frequent resistance to several antibiotics in certain bacterial species. A potential copper threshold concentration could not be

⁷ <http://www.efsa.europa.eu/en/efsajournal/pub/2967.htm>

derived. The total pool of macrolide resistance in animals originates probably from antibiotic treatment and not from the use of high dietary copper. The amount to which copper-resistant bacteria contribute to the overall antibiotic resistance can presently not be quantified.

The opinion was adopted.⁸

5.9. Zinc oxide for all species (EFSA-Q-2011-00844)

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 zinc oxide as a nutritional additive for all animal species.

The draft opinion was discussed. The FEEDAP Panel concluded that the additive is safe for the target species and consumers. The zinc oxide under application is considered a compound with high dusting potential, which may result in a critical exposure of users by inhalation, affecting the respiratory system. The authorised use of zinc as a feed additive does not pose direct concern for agricultural soil compartment; however, there is a potential environmental concern related to groundwater, drainage and run-off of zinc to surface water. Zinc oxide is efficacious in meeting animals' zinc requirements.

The opinion was adopted.⁹

5.10. Vitamin D₃ (cholecalciferol) for chickens for fattening, turkeys, other poultry, piglets (suckling), pigs, calves for rearing, calves for fattening, bovines, ovines, equines, all fish species and categories (EFSA-Q-2011-00950)

A member of the working group presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation of a new use under Article 4 of Regulation (EC) No 1831/2003 of Vitamin D₃ (cholecalciferol) as a nutritional additive for chickens for fattening, turkeys, other poultry, piglets (suckling), pigs, calves for rearing, calves for fattening, bovines, ovines, equines, all fish species and categories.

The draft opinion was discussed. The Panel noted that for turkeys for fattening, equines, bovines, ovines and pigs the maximum content for vitamin D₃ does not provide any margin of safety, and that, except for pigs, the maximum content is above the upper safe level, according to the National Research Council data when fed for more than 60 days. On the other hand, no safety concern is identified for the use of vitamin D₃ in chickens for fattening and fish. Notwithstanding the long history of supplementing compound feed with vitamin D and the absence of publicly reported intolerances, the FEEDAP Panel is not in the position to draw final conclusions on the safety of vitamin D and considers the current maximum contents as temporarily acceptable. Any additional administration of vitamin D₃ via water for drinking represents a safety concern. The Panel concluded that vitamin D₃ is safe for the consumer and the environment. Vitamin D₃ is not an irritant to skin and eyes and not a skin sensitizer. Inhaled vitamin D₃ is highly toxic; exposure to dust is harmful to persons handling the additive. The vitamin D₃ under application is regarded as an effective dietary source of the vitamin in animal nutrition.

⁸ <http://www.efsa.europa.eu/en/efsajournal/pub/2969.htm>

⁹ <http://www.efsa.europa.eu/en/efsajournal/pub/2970.htm>

The opinion was adopted.¹⁰

5.11. Seleno-Hydroxy-Analogue of Methionine for all animal species (EFSA-Q-2012-00058)

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 the additive Seleno-Hydroxy-Analogue of Methionine as a nutritional additive for all animal species.

The draft opinion was discussed. The discussion was not finalised and therefore the opinion will be submitted to the next Plenary meeting for discussion and possible adoption.

6. New Mandates

6.1. New applications under Regulation (EC) No 1831/2003

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 them:

EFSA-Q-Number	Subject
EFSA-Q-2012-00905	Quantum Blue (6-phytase) for laying hens, minor laying poultry species
EFSA-Q-2012-00906	Monimax (Monesin sodium and nicarbazin) for turkeys for fattening
EFSA-Q-2012-00909	AGal-Pro (Alpha-galatosidase and endo-1,4beta-glucanase) for chickens reared for laying, minor poultry species for fattening
EFSA-Q-2012-00919	Coxiril [®] (Diclazuril) for turkeys for fattening
EFSA-Q-2012-00920	L-Valine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM80058 (L-Valine feed grade) for all animal species

6.2. Questions received under Regulation (E) No 178/2002

EFSA-Q-Number	Subject
EFSA-Q-2012-00925	Biosprint [®] (<i>Saccharomyces cerevisiae</i> MUCL 39885) for cattle for fattening

6.3. 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-2012-00661	Tartrazine for dogs and cats, ornamental fish, grain-eating ornamental birds, small rodents	08/11/2012

¹⁰ <http://www.efsa.europa.eu/en/efsajournal/pub/2968.htm>

7. Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA, the European Commission

- The Panel was informed on specialised training for panel members and scientific staff being organised by EFSA.

8. Other scientific topics for information and/or discussion

Not discussed

9. Any other business

Not discussed

Annex

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF THE ANNUAL DECLARATION OF INTERESTS (ADoI) OR THE SPECIFIC DECLARATION OF INTEREST (SDoI)

In the ADoI or SDoI filled for the present meeting Dr John Wallace declared the following interest: Vitamin D3 (cholecalciferol) for chickens for fattening, turkeys, other poultry, piglets (suckling), pigs, calves for rearing, calves for fattening, bovines, ovines, equines, all fish species and categories (EFSA-Q-2011-00950). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests and the Decision of the Executive Director implementing this Policy, 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 the impossibility for the expert to be present when those item is discussed, voted or in anyway processed by that concerned scientific group.