European Food Safety Authority

FEED UNIT

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

Minutes of the 92nd Plenary Meeting

Held on 11-13 December 2012, Parma

(Agreed on 29 January 2013)

Participants

- **Panel Members**

  Gabriele Aquilina, Alex Bach,[1] Vasileios Bampidis, Maria De Lourdes Bastos, Gerhard Flachowsky, Josep Gasa-Gasó, Mikolaj Antoni Gralak, Christer Hogstrand, Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Derek Renshaw, Guido Rychen,[2] Maria Saarela,[3] Patrick van Beelen, John Wallace and Johannes Westendorf.

- **Hearing Experts**

  Jürgen Gropp[4] (for items 5.2, 5.5 and 5.13)

- **European Commission**

  Christoph von Holst (DG JRC)[5]

- **EFSA**

  - **Feed Unit:** Claudia Roncancio-Peña, Jaume Galobart, Gloria López-Gálvez, Paola Manini, Maria Vittoria Vettori, Matteo Lorenzo Innocenti, Rosella Brozzi and Nicola Jane Reynolds.
  - **Other EFSA Directorates/Units:** N/A

1. Welcome and apologies for absence

The Vice-Chair welcomed the participants.

Apologies were received from Kristen Sejrsen.

2. Adoption of agenda

The agenda was adopted after the deletion of "Chemically defined flavourings from Flavouring Group 20 - Aliphatic and aromatic mono- and di-thiols and mono-, di-, tri-, and polysulfides with or without additional oxygenated functional group for all animal species and categories (EFSA-Q-2010-00998)" and "Calcium iodate anhydrous and potassium iodide for

1 Present only on 11 and 12 December.
2 Present only on 11 and 12 December.
3 Present only on 11 and 12 December.
4 Present only on 12 December.
5 Present only on 12 December.

all animal species (EFSA-Q-2011-00744)" and the addition of "Hostazym X (endo-1,4-beta-xylanse) for chickens for fattening, turkeys for fattening, laying hens, weaned piglets, fattening pigs and other birds for fattening or laying (EFSA-Q-2010-00036)" and "*Lactobacillus plantarum* (NCIMB 30083) *and Lactobacillus plantarum* (NCIMB 30084) as silage additives (EFSA-Q-2012-00090)".

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 and the Specific Declaration of Interests 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 91st Plenary meeting held on 13-15 November 2012, Barcelona

The minutes of the 91st Plenary meeting were reviewed and agreed.[6]

5. Scientific outputs submitted for discussion and possible adoption[7]

5.1. Hostazym X (endo-1,4-beta-xylanse) for chickens for fattening, turkeys for fattening, laying hens, weaned piglets, fattening pigs and other birds for fattening or laying (EFSA-Q-2010-00036)

Not discussed due to lack of time

5.2. Vitamin A (retinol acetate, retinol palmitate, retinol propionate) for all animal species (EFSA-Q-2010-01294)

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 vitamin A as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that the use of vitamin A up to the maximum contents is safe for the target animals and the environment. All consumer exposure calculations showed that liver is the only food of animal origin whose consumption poses a risk to the adult consumers. This risk can be considerably reduced, however not eliminated, if the new levels proposed by EFSA for a reduction of the maximum vitamin A content in feedingstuffs would be respected. The FEEDAP Panel made a proposal on the maximum content of vitamin A in complete feed, milk replacers or a maximum daily intake for the target species and categories of target species. The availability of an additional route of administration of vitamin A (e.g., water for drinking) would increase the risk for the consumer. Retinyl esters are irritants to skin and potential skin sensitizers. Data on respiratory toxicity and on the levels of exposure of workers which would cause systemic or respiratory toxicity are not available. However, inhalation exposure of workers from handling certain formulations is likely. Retinyl esters are regarded as effective sources of vitamin A.

The opinion was adopted.[8]

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6 http://www.efsa.europa.eu/en/events/event/121113b-m.pdf

7 During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.

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

The rapporteur 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 Panel concluded that the additive is safe for all animal species/categories considering that its use in supplementing feed is first limited by the regulatory maximum content of zinc; however, its contribution to dietary methionine needs consideration when formulating diets. The use of methionine-zinc in animal nutrition is safe for consumers when used up to the maximum authorised zinc level. The compound should be considered as a potential irritant to skin and eye and a skin sensitiser. Zinc compounds are hazardous by inhalation; methionine-zinc shows high dusting potential, exposure by inhalation represents therefore a hazard to persons handling the additive. The use of methionine-zinc in feed as a source of zinc does not pose an additional risk to the environment, compared with other sources of zinc for which it will substitute, as long as the maximum authorised content in feedingstuffs is not exceeded. Methionine from the additive does not represent a risk to the environment. The additive is considered an efficacious source of zinc for all animal species/categories and it has some potential to be an effective source of methionine in ruminants.

The opinion was adopted.[9]

5.4. Patent Blue V for all animal species (EFSA-Q-2010-1529)

The rapporteur 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 Patent Blue V as a sensory additive for all animal species.

The draft opinion was discussed. The opinion will be submitted to the next Plenary meeting for possible adoption.

5.5. Carophyll Red (canthaxanthin) for all poultry for breeding purposes (chickens, turkeys and other poultry) (EFSA-Q-2011-00083)

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 Carophyll Red (canthaxanthin) as a zootechnical additive for all poultry for breeding purposes.

The draft opinion was discussed. The Panel concluded that the use of the additive under the proposed conditions is safe for the target species, the consumer and the environment. Canthaxanthin is not an irritant to skin and eyes and unlikely to be a skin sensitiser. However, in the absence of specific data for the additive, the Panel considered it prudent to treat the additive as an irritant to skin and eyes and a skin sensitiser. The Panel also concluded that the additive has the potential to stabilise the reproductive performance of breeder hens. However, an extrapolation of this conclusion to other breeder poultry species was not possible owing to inconsistencies

8 http://www.efsa.europa.eu/en/efsajournal/pub/3037.htm
9 http://www.efsa.europa.eu/en/efsajournal/pub/3038.htm

in the timing of the effects observed and the absence of a scientifically sound explanation on the mode of action.

The opinion was adopted.[10]

5.6. Formaldehyde for all animal species (EFSA-Q-2011-00333)

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 formaldehyde as a technological additive for all animal species.

An initial discussion took place. The opinion will be submitted to discussion and possible adoption in a future plenary meeting.

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

The Chair of the Working Group presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of *Bacillus amyloliquefaciens* (NCIMB 30229) as a silage additive for all animal species.

The draft opinion was discussed. The Panel concluded that the strain produces cyclic lipopeptides which possess potent surfactant activity known to be involved in food intoxication. Therefore, the use of the strain in the production of silage presents a hazard for consumers, users and environment, and potentially also to the target animals. The potential of the additive to improve aerobic stability of silages at the proposed dose of 5.0×10^7 CFU/kg fresh materials was not convincingly demonstrated.

The opinion was adopted.[11]

5.8. Orthophosphoric acid for all animal species (EFSA-Q-2011-00419)

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 orthophosphoric acid as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that orthophosphoric acid is safe for all animal species when used as a preservative provided that the optimal Ca:P ratio is maintained. Since the maximum tolerable content of dietary phosphorus for all animal species is well known, setting a maximum content for the additive is not considered necessary. The Panel also concluded that orthophosphoric acid is safe for the consumer and the environment. It is corrosive for skin and eyes and should be considered as hazardous for the respiratory tract. Since orthophosphoric acid is used in food as preservative and its function in feed it is essentially the same of that in food, no further demonstration of efficacy is necessary. It is thus expected that orthophosphoric acid would have the potential to contribute to the preservation of liquid feeds and sustain the quality of water for drinking.

[10] http://www.efsa.europa.eu/en/efsajournal/pub/3047.htm
[11] http://www.efsa.europa.eu/en/efsajournal/pub/3042.htm

The opinion was adopted.[12]

5.9. Seleno-hydroxy-analogue of methionine (Selisseo®) 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 product Seleno-hydroxy-analogue of methionine as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is safe for all species/categories up to the maximum authorised total selenium level in complete feed. To ensure consumer safety from consumption of food originating from animals supplemented with the additive, the FEEDAP Panel concluded that selenium supplementation from the additive should not exceed a maximum of 0.2 mg Se/kg complete feed. The additive should be regarded as an eye irritant. Inhalation exposure poses a hazard to users; the FEEDAP Panel concludes, therefore, that the formulation and conditions of use of the solid form of the additive should minimise user exposure by inhalation. The use of the additivein feed does not pose an additional risk to the environment, compared to other sources of selenium for which it will substitute, as long as the maximum authorised content in feedingstuffs is not exceeded. The additive is an effective source of selenium for all animal species/categories, and it does not modify the quality of meat as measured by physico-chemical properties.

The opinion was adopted.[13]

5.10. *Lactobacillus plantarum* (NCIMB 30083) and *Lactobacillus plantarum* (NCIMB 30084) as silage additives (EFSA-Q-2012-00090)

The Chair of the Working Group presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of *Lactobacillus plantarum* (NCIMB 30083) and *L. plantarum* (NCIMB 30084) as silage additives for all animal species.

The draft opinion was discussed. The Panel concluded that the use of the strains in the production of silage is presumed safe for livestock species, consumers of products from animals fed the treated silage and for the environment. In the absence of data, the potential of both strains to be irritants and/or to act as skin sensitisers cannot be totally excluded. The additives should be considered to have the potential to be a skin/respiratory sensitiser and treated accordingly. Both strains of *L. plantarum* have the potential to improve the production of silage by increasing the preservation of dry matter, by reducing the pH and increasing the lactic acid with easy and moderately difficult to ensile forage species. There was evidence of reduced protein degradation as indicated by the lower ammonia-N content of ensiled material.

The opinion was adopted.[14]

12 http://www.efsa.europa.eu/en/efsajournal/pub/3043.htm
13 http://www.efsa.europa.eu/en/efsajournal/pub/3046.htm
14 http://www.efsa.europa.eu/en/efsajournal/pub/3041.htm

5.11. *Enterococcus faecium* (CNCM I-3236) as a silage additive for all animal species (EFSA-Q-2012-00093)

A member of the Working Group presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of *Enterococcus faecium* (CNCM I-3236) as a silage additive for all animal species.

The draft opinion was discussed. The Panel concluded that the use of this strain of *E. faecium* in animal nutrition is not expected to raise concerns for livestock species, consumers or the environment. The preparations containing the strain may cause irritation upon contact with skin and eyes. The additive should be considered to have the potential to be a skin/respiratory sensitiser. The FEEDAP Panel is unable to conclude on the benefit of using the strain of *E. faecium* as a silage additive for all forage species.

The opinion was adopted.[15]

5.12. Cylactin®/Cernivet® (*Enterococcus faecium* NCIMB 10415) for cats and dogs (EFSA-Q-2012-00420)

Not discussed due to lack of time

5.13. Coxidin® (Monensin sodium) for chickens for fattening and chickens reared for laying (EFSA-Q-2012-00557)

The Chair of the Working Group presented the question and the draft opinion. This question refers to the modification of the conditions of authorisation under Article 13 of Regulation (EC) No 1831/2003 of the product Coxidin® (monensin sodium). The applicant is seeking a reduction of the withdrawal time from one to zero days.

The draft opinion was discussed. The Panel concluded that the data provided does not support the reduction of the withdrawal period from one day to zero days for Coxidin® administered in feed for chickens for fattening and chickens reared for laying at the authorised concentration.

The opinion was adopted.[16]

5.14. Miya-Gold (*Clostridium butyricum* FERM BP-2789) for chickens for fattening, chickens reared for laying, minor avian species for fattening and to point of lay (EFSA-Q-2012-00575)

The Chair of the Working Group presented the question and the draft opinion. This question refers conditions of authorisation under Article 13 and the authorisation of a new use under Article 4 of Regulation (EC) No 1831/2003 of the product Miya-Gold (*Clostridium butyricum* FERM BP-2789) as a zootechnical additive for chickens for fattening, chickens reared for laying, minor avian species for fattening and to point of lay.

The draft opinion was discussed. The FEEDAP Panel concluded that the additive is safe for the target species under application. Based on a meta-analysis from the five trials presented, the Panel concluded that the additive has some potential to improve performance of chickens for fattening at the lower dose. This conclusion can be

[15] http://www.efsa.europa.eu/en/efsajournal/pub/3044.htm
[16] http://www.efsa.europa.eu/en/efsajournal/pub/3045.htm

extended to chickens reared for laying and extrapolated to minor avian species (other than those used for laying).

The opinion was adopted.[17]

5.15. Clinoptilolite of sedimentary origin for all animal species (EFSA-Q-2012-00582)

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 clinoptilolite of sedimentary origin as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that clinoptilolite at a dose of 10 000 mg/kg complete feed could be considered safe for all animal species. Clinoptilolite is safe for the consumer and the environment and should be considered as an irritant to skin and eyes, a dermal sensitiser and an inhalation toxicant. The Panel also concluded that the additive is considered to have the potential to be effective as an anticaking agent and as pellet binder.

The opinion was adopted.[18]

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-2012-00942	DL-Methionyl-DL-Methionine for fish, all aquatic animals including crustaceae
EFSA-Q-2012-00947	Complexation products of sodium tartrates with iron(III) chloride for all animal species
EFSA-Q-2012-00953	Vitamin B2 (riboflavin) for all animal species
EFSA-Q-2012-00954	Vitamin B2 - riboflavin for all animal species
EFSA-Q-2012-00955	Riboflavin sodium phosphate for all animal species

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

EFSA-Q-Number	Subject
EFSA-Q-2012-00966	Request for an opinion on authorisation under Regulation (EC) No 1831/2003 on additives for use in animal nutrition (group of applications for zinc)
EFSA-Q-2012-00913	BioPlus® 2B *(Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750) for sows

[17] http://www.efsa.europa.eu/en/efsajournal/pub/3040.htm
[18] http://www.efsa.europa.eu/en/efsajournal/pub/3039.htm

6.3. Self-task

EFSA-Q-Number	Subject
EFSA-Q-2012-00962	Proposal for a self-task by the FEEDAP Panel to produce a guidance document for the renewal of the authorisation of feed additives

6.4. 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
1	EFSA-Q-2010-01044	Suilectin™ (Lectins isolated from kidney bean - *Phaseolus vulgaris*) for piglets (suckling)	03/12/2012
2	EFSA-Q-2012-00407	Stenorol® (Halofuginone hydrobromide) for chickens for fattening and turkeys	15/11/2012
3	EFSA-Q-2012-00694	L-Valine for all animal species	12/11/2012
4	EFSA-Q-2012-00789	Lenziaren (Iron aqua carbonate hydroxy oxo starch sucrose complex) for cats	22/11/2012

These applications were assigned to the WG on Suilectin (#1), Coccidiostats (#2), Amino acids (#3) and Other Zootechnical additives (#4).

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

- The Panel was informed that the Executive Director has accepted the proposal of the Panel regarding a self-task to produce a guidance document for the renewal of the authorisation of feed additives (EFSA-Q-2012-00962, see 6.3 above). A new working group will be created to address this mandate.

8. Other scientific topics for information and/or discussion

- Christoph von Holst made a presentation about the role of the European Union Reference Laboratory in the process of authorisation of feed additives.
- Discussion took place on the acceptable quality parameters of water for drinking for use in animal nutrition.
- The Panel was informed about the EU Project NOSHAN 'Sustainable Production of Functional and safe Feed from Food Waste'.

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 Alex Bach declared the following interest: *Enterococcus faecium* (CNCM I-3236) as a silage additive for all animal species (EFSA-Q-2012-00093). 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 this item is discussed, voted on or in anyway processed by that concerned scientific group.

In the ADoI or in the SDoI filled for the present meeting Prof. Josep Gasa-Gasó declared the following interest: *Enterococcus faecium* (CNCM I-3236) as a silage additive for all animal species (EFSA-Q-2012-00093), *Bacillus amyloliquefaciens* (NCIMB 30229) as a silage additive for all animal species (EFSA-Q-2011-00389) and *Lactobacillus plantarum* NCIMB 30083 *and L. plantarum* NCIMB 30084 as silage additives (EFSA-Q-2012-00090). 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 items are discussed, voted on or in anyway processed by that concerned scientific group.

In the ADoI or SDoI filled for the present meeting Dr John Wallace declared the following interest: Carophyll Red for (canthaxanthin) for turkeys for breeding and other poultry for breeding (EFSA-Q-2011-00083) and Cylactin®/Cernivet® (*Enterococcus faecium* NCIMB 10415) for cats and dogs (EFSA-Q-2012-00420). 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 items are discussed, voted on or in anyway processed by that concerned scientific group.