

FEED UNIT

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

Minutes of the 89th Plenary Meeting
Held on 11-13 September 2012, Parma

(Agreed on 16 October 2012)

Participants

- **Panel Members**

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

- **Hearing Experts**

Jürgen Gropp³ (for item 5.4)

- **European Commission**

Jim Moynagh⁴

- **EFSA**

- **Feed Unit:** Claudia Roncancio-Peña, Jaume Galobart, Gloria López-Gálvez, Paola Manini, Maria Vittoria Vettori, Lucilla Gregoretta, Rosella Brozzi, Matteo Lorenzo Innocenti, and Nicola Jane Reynolds.
- **Other EFSA Directorates/Units:** Juergen De Maggio,⁴ Francesco Ciancio⁴ and Jean-Lou Dorne⁴

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Secundino López-Puente and Giovanna Martelli.

2. Adoption of agenda

The agenda was adopted without changes.

¹ Present only on 12 and 13 September.

² Present only on 11 and 12 September.

³ Present only on 12 September (PM) and 13 September.

⁴ Present only on 13 September.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests⁵ and the Decision of the Executive Director implementing this Policy⁶, 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 ADol and SDol please refer to the Annex.

4. Agreement of the minutes of the 88th Plenary meeting held on 3-4 July 2012, Parma

The minutes of the 88th Plenary meeting were reviewed and agreed.⁷

5. Scientific outputs submitted for discussion and possible adoption

5.1. Roxazyme[®] G2 G/L (endo-1,4-beta-glucanase, endo-1,(3)4-beta-glucanase and endo-1,4-beta-xylanase) for chickens and turkeys for fattening, laying hens, ducks, poultry and piglets (weaned) (EFSA-Q-2007-185)

Not discussed due to lack of time.

5.2. Chemically defined flavourings from Chemical Group 02 - Branched-chain primary aliphatic alcohols/aldehydes/acids, acetals and esters for all animal species (EFSA-Q-2010-00701)

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 under Article 4 of Regulation (EC) No 1831/2003 of the chemically defined flavourings from Chemical Group 02 as sensory additives for all animal species.

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

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 opinion will be submitted to the next Plenary meeting for discussion and possible adoption.

5.4. Carophyll[®] Red (canthaxanthin) for turkeys for breeding and other poultry for breeding (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 the product Carophyll

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

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

⁷ <http://www.efsa.europa.eu/en/events/event/120703-m.pdf>

Red (canthaxanthin) as a zootechnical additive for turkeys for breeding and other poultry for breeding.

The draft opinion was discussed. The Panel identified the need for supplementary data in order to reach a conclusion. The applicant will be contacted and requested to provide the additional information.

5.5. Nicotinic acid (niacin) and nicotinic acid amide (nicotinamide-niacinamide) for all animal species (EFSA-Q-2011-00262)

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 nicotinic acid (niacin) and nicotinic acid amide (nicotinamide-niacinamide) as nutritional additives for all animal species.

The draft opinion was discussed. The Panel concluded that niacin is safe for the target animals, the consumer and the environment. Nicotinic acid and nicotinamide are not irritant to skin, but can cause irritancy to eyes and mucous membranes. They are unlikely to cause skin sensitisation. Workers might be exposed to a respirable dust when handling nicotinic acid, which should be regarded as being potentially harmful to their health. Nicotinic acid and nicotinamide are regarded as an effective source of niacin in animal nutrition.

The opinion was adopted.

5.6. Sodium hydroxide for dogs, cats and ornamental fish (EFSA-Q-2011-00279)

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 sodium hydroxide as a technological additive for all animal species.

The draft opinion was discussed. The Panel concluded that sodium hydroxide is considered safe for the target animals, provided that the resulting total sodium concentration in feed does not compromise the overall electrolyte balance. Sodium hydroxide in solid form and in aqueous solution at concentrations > 8.0% is corrosive. At lower concentrations it is irritant to skin, eyes and the respiratory tract. Exposure via inhalation is likely to be minimal. Sodium hydroxide is not considered to be a skin sensitiser. The FEEDAP Panel also concluded that, since sodium hydroxide is used in food as acidity regulator and its function in feed is essentially the same of that in food, no further demonstration of efficacy is necessary.

The opinion was adopted.⁸

5.7. *Lactobacillus salivarius* (ATCC 11741/CNCM I-3238) and *Lactobacillus casei* (LC 32909/ATCC PTA-6135) for all animal species (EFSA-Q-2011-00381)

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 *Lactobacillus salivarius* (ATCC 11741/CNCM I-3238) and *Lactobacillus casei* (LC 32909/ATCC PTA-6135) as silage additives for all animal species.

⁸ <http://www.efsa.europa.eu/en/efsajournal/pub/2882.htm>

The draft opinion was discussed. The Panel concluded that the use of these strains is presumed safe for livestock species, consumers of products from animals fed the treated silage and for the environment. The indicative data on particle size distribution of the *L. casei* product and the proteinaceous nature and high dusting potential of both products indicate a toxic hazard by exposure via a respiratory route for those handling the additives, with a consequent risk of sensitisation. The additive containing *L. casei* has the potential to improve the production of silage from easy to ensile material by reducing the pH and increasing the preservation of dry matter. The additive containing the *L. salivarius* strain showed limited potential to reduce dry matter loss in moderately difficult and difficult to ensile forage species. However, given that the magnitude of the response to the additive in the studies provided was small and the effects inconsistent, the FEEDAP Panel is doubtful of the benefits that may be provided by the use of this additive in the ensiling process.

The opinion was adopted.⁹

5.8. *Lactobacillus buchneri* (NCIMB 30139) for all animal species (EFSA-Q-2012-00088)

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 *Lactobacillus buchneri* (NCIMB 30139) as a silage additive for all animal species.

The draft opinion was discussed. The Panel concluded that the use of this strain is presumed safe for livestock species, consumers of products from animals fed the treated silage and for the environment. Indicative data on particle size distribution and the proteinaceous nature of the active agent indicate a possible hazard for those handling the additive of exposure by a respiratory route with a consequent risk of sensitisation. Eight studies gave consistent and significant results showing that the additive containing the *L. buchneri* strain has the potential to improve the preservation of silage by increasing acetic acid production resulting in an extended aerobic stability of the treated silage.

The opinion was adopted.¹⁰

5.9. Bactocell (*Pediococcus acidilactici*) for fish (EFSA-Q-2012-00441)

A member of the working group presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the efficacy of Bactocell (*Pediococcus acidilactici*) as a zootechnical additive for fish. The FEEDAP Panel delivered an opinion on the safety and efficacy of the same additive for fish.¹¹

The draft opinion was discussed. The Panel concluded that Bactocell has the potential to produce a beneficial effect in development, increasing the proportion of well conformed fish. The effects seen were comparable to those seen earlier in salmonids.

The opinion was adopted.¹²

⁹ <http://www.efsa.europa.eu/en/efsajournal/pub/2884.htm>

¹⁰ <http://www.efsa.europa.eu/en/efsajournal/pub/2883.htm>

¹¹ <http://www.efsa.europa.eu/en/efsajournal/pub/1037.htm>

¹² <http://www.efsa.europa.eu/en/efsajournal/pub/2886.htm>

6. Scientific outputs submitted for discussion

6.1. 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.

An initial discussion took place. The opinion will be submitted to the next Plenary meeting for discussion and possible adoption.

6.2. Panaferd AX (Red carotenoid-rich bacterium *Paracoccus carotinifaciens*) for ornamental fish (EFSA-Q-2012-00064)

A member 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 Panaferd AX (red carotenoid-rich bacterium *Paracoccus carotinifaciens*) as a sensory additive for ornamental fish.

The draft opinion was discussed. The opinion will be submitted to a future Plenary meeting for adoption once the report from the European Union Reference Laboratory is available.

6.3. Toyocerin (*Bacillus cereus*) for sows, piglets, pigs for fattening, cattle for fattening, calves for rearing, chickens for fattening and rabbits for fattening (EFSA-Q-2010-01095 & EFSA-Q-2011-00832)

The Opinion was introduced to the Panel and briefly discussed but further discussion is needed.

7. New Mandates

7.1. 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-2012-00693	Quantum Blue (6-phytase) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor poultry species, piglets (weaned), fattening pigs and sows
EFSA-Q-2012-00694	L-Valine for all animal species
EFSA-Q-2012-00719	BioMin® BBSH 797 - DSM 11798 Genus nov. (formerly <i>Eubacterium</i>) species nov. for all animal species
EFSA-Q-2012-00727	AveMix® XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for pigs for fattening and minor porcine species

7.2. Other mandates

EFSA-Q-Number	Subject
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EFSA-Q-2012-00689	CFT/EFSA/FEED/2012/01: Inventory of food additives/food contact materials/feed additives applications in the area of nanotechnologies
EFSA-Q-2012-00705	CFT/EFSA/FEED/2012/04: Extensive Literature Search on the bioavailability of selected trace elements in animal nutrition: Incompatibilities and interactions when combined with other feed additives or component of the animal diet

7.3. 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-2012-00303	Clinacox [®] 0.5% (diclazuril) for chickens reared for laying	13/08/2012
EFSA-Q-2012-00398	Omega-6-fatty acid as octadecadienoic acid (conjugated linoleic acid-methylester) for all animal species	19/07/2012
EFSA-Q-2012-00421	Provita LE (<i>Enterococcus faecium</i> DSM 7134 and <i>Lactobacillus rhamnosus</i> DSM 7133) for calves for rearing	05/07/2012
EFSA-Q-2012-00454	Oralin [®] (<i>Enterococcus faecium</i> DSM 10663 NCIMB 10415) for calves for rearing, piglets (suckling and weaned), chickens for fattening, poultry, turkeys for fattening and dogs	02/08/2012
EFSA-Q-2012-00535	Lutein for poultry, crustaceans, fish/tilapias, cats and dogs, ornamental fish and birds	23/07/2012
EFSA-Q-2012-00557	Coxidin [®] (Monensin sodium) for chickens for fattening, chickens reared for laying, turkeys	20/07/2012
EFSA-Q-2012-00633	Coxiril [®] (Diclazuril) for chickens for fattening	07/08/2012
EFSA-Q-2012-00645	<i>Lactobacillus kefir</i> BIO 94 IFA 94, DSM 19455 for all animal species	04/09/2012
EFSA-Q-2012-00668	AveMix [®] XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for turkeys for fattening	30/07/2012
EFSA-Q-2012-00719	BIOMIN [®] BBSH 797 - DSM 11798 Genus nov. (formerly <i>Eubacterium</i>) species nov. for all animal species	30/08/2012
EFSA-Q-2012-00727	AveMix [®] XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for pigs for fattening and minor porcine species	22/08/2012

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

- The Scientific Committee of EFSA has set Working Groups on Botanicals Compendium, QPS for Botanicals, Emerging risks, Guidance review, Uncertainty/Terminology/ Transparency and Environmental Risk Assessment.
- A presentation from the Emerging Risks Unit of EFSA on the assessment of Chemical mixtures was given to the Panel.

9. Other scientific topics for information and/or discussion

Not discussed

10. Any other business

- The dates for the plenaries of the FEEDAP Panel for 2013 were set: 29-31 January, 12-14 March, 16-18 April, 14-16 May, 18-20 June, 9-11 July, 10-12 September, 8-10 October, 5-7 November and 3-5 December.
- The Chair of the Panel nominated the Chairs and Vice-Chairs of the different Standing Working Groups.
- The Panel were informed about the new centralised system for meeting organisation by representatives of the CORSER Unit of EFSA.

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: Roxazyme® G2 G/L (endo-1,4-beta-glucanase, endo-1,(3)4-beta-glucanase and endo-1,4-beta-xylanase) for chickens and turkeys for fattening, laying hens, ducks, poultry and piglets (weaned) (EFSA-Q-2007-185), Bactocell (*Pediococcus acidilactici*) for fish (EFSA-Q-2012-00441) and Toyocerin (*Bacillus cereus*) for sows, piglets, pigs for fattening, cattle for fattening, calves for rearing, chickens for fattening and rabbits for fattening (EFSA-Q-2010-01095 & EFSA-Q-2011-00832). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (Dols) 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 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: research contracts with the producer of Toyocerin (EFSA-Q-2010-01095 and EFSA-Q-2011-00832). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (Dols) 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 that item is discussed, voted on or in anyway processed by that concerned scientific group.