MINUTES OF THE 82ND PLENARY MEETING

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

(PARMA, 13-15 DECEMBER 2011)

(AGREED ON 31 JANUARY 2012)

PARTICIPANTS

Panel Members
Gabriele Aquilina, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Noël Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle (2nd and 3rd days), Christer Hogstrand, Reinhard Kroker, Lubomir Leng, Secundino López Puente, Anne-Katrine Lundebye Haldorsen, Alberto Mantovani, Giovanna Martelli, Miklós Mézes, Derek Renshaw, Maria Saarela, and Kristen Sejrsen.

Apologies
Ingrid Halle (1st day) and Johannes Westendorf.

EFSA
Claudia Roncancio-Peña, Jaume Galobart, Matteo Lorenzo Innocenti, Rosella Brozzi, Irene Bustos Sepúlveda, Maria Vittoria Vettori, Paola Manini, Lucilla Gregoretti, Jordi Tarrés-Call and Nicola Jane Reynolds.

European Commission
Marina Marini (DG SANCO).

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 82nd Plenary meeting of the FEEDAP Panel.

Members not able to attend the meeting sent their apologies (see under participants).

2. ADOPTION OF THE AGENDA

The agenda was adopted after deletion of the item on *Duddingtonia flagrans* for sheep (EFSA-Q-2005-051).

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

4. ADOPTION OF THE DRAFT MINUTES OF THE 81ST PLENARY MEETING

The minutes of the 81st Plenary meeting of the Panel held on 15-17 November 2011 were reviewed and agreed.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Rosemary extract liquid of natural origin for dogs and cats (EFSA-Q-2004-176)**

  The Chair of the Panel presented the question and the draft opinion. This question refers to the authorisation under Article 4(1) of Regulation (EC) No 1831/2003 of the product Rosemary extract liquid of natural origin as a technological additive for dogs and cats.

  The draft opinion was discussed. During the assessment of the technical dossier, the applicant was requested to provide additional information. The applicant failed to provide the additional information even after several requests by EFSA. Therefore, considering the data provided in the original dossier and the absence of response from the applicant to the requests from EFSA, the FEEDAP Panel was not in a position to deliver an opinion on the safety and efficacy of this additive.

  The opinion was adopted.[2]

- **Chemically defined flavourings. Group 25 - Phenol derivatives containing ringalkyl, ring-alkoxy, and side-chains with an oxygenated functional group for all species and categories (EFSA-Q-2009-00882)**

  The Chair of the Working Group (WG) presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and authorisation of new use under Article 4 of Regulation (EC) No 1831/2003 of the flavourings from the Chemical Group 25 as sensory additives for all species.

  The draft opinion was discussed. An initial discussion took place, and the Panel made comments that require further discussion at the working group level.

- **Update of the "Guidance for the preparation of dossiers for technological additives to include the new functional group 'substances for reduction of the contamination of feed by mycotoxins'" (EFSA-Q-2010-00017) and Update of the "Guidance for the preparation of dossiers by categories of feed additives – Technological additives" (EFSA-Q-2010-00902)**

  The Rapporteur presented the questions. The Panel through these self-tasks intended to update the guidance for the preparation of dossiers for technological additives. In the preparation of this guidance, recent technological progress and scientific development, and the practical experience of the Panel have been taken into account. In addition, they include the requirements for the new functional group of 'substances for reduction of the contamination of feed by mycotoxins'.

  The changes proposed were initially discussed during the October Plenary. The guidance was adopted.[3]

- **Ronozyme® HiPhos L and M (6-phytase) for all pigs and poultry (EFSA-Q-2010-00769)**

[1] http://www.efsa.europa.eu/en/events/event/111115-m.pdf

[2] http://www.efsa.europa.eu/en/efsajournal/pub/2526.htm

[3] http://www.efsa.europa.eu/en/efsajournal/pub/2528.htm

The Rapporteur presented the question and the draft opinion. This question refers authorisation under Article 4 of Regulation (EC) No 1831/2003 of the product Ronozyme HiPhos as a zootechnical feed additive for pigs and poultry. This additive is based on a 6-phytase produced by a genetically modified strain of *Aspergillus oryzae*. The safety of the genetic modification was assessed by the GMO Panel.

The draft opinion was discussed. It was concluded that the final product does not trigger any safety concern with regard to its genetic modification. The additive is also considered safe for poultry and pigs when used at the maximum recommended dose, and no safety concerns are foreseen for the consumer and the environment. The product is not an irritant to skin or eye, but should be considered as a skin sensitiser. The additive has the potential to improve phosphorus utilization in poultry and pigs for fattening at the minimum dose of 500 FYT/kg complete feed, and at the minimum dose of 1000 FYT/kg complete feed for sows.

The opinion was adopted.[4]

- **Chemically defined flavourings from Chemical Group 17 - Propenylhydroxybenzenes for all animal species and categories (EFSA-Q-2010-01035)**

The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and authorisation of new use under Article 4 of Regulation (EC) No 1831/2003 of the flavourings from the Chemical Group 17 as sensory additives for all species.

The draft opinion was discussed. The use of isoeugenol as a flavour in fish and other aquatic species is contra-indicated. The FEEDAP Panel concluded that the range of use levels of 1 to 5 mg/kg feed proposed by the applicant for isoeugenol is safe for all animal species (except fish) with a margin of safety in the range of 1 to 4. Considering the low margin of safety, the simultaneous administration of isoeugenol in feed and water for drinking for poultry should be avoided. The use of the additive as flavour in non-dairy mammals at 5 mg/kg feed is considered safe for the consumers, although the lack of data on metabolism and residues in all other species and categories precludes an assessment of consumer exposure from these sources. The FEEDAP Panel considers isoeugenol as an irritant to respiratory system, skin and eyes, and as a skin and respiratory sensitiser. The use of the additive in animal nutrition at the levels proposed is expected to be safe for the environment. Since isoeugenol is used in food as flavouring, and its function in feed is essentially the same as that in food no further demonstration of efficacy is necessary.

The opinion was adopted.[5]

- **Update of the "Guidance for the preparation of dossiers by categories of feed additives – Sensory additives" (EFSA-Q-2010-01157)**

The Rapporteur presented the question. The Panel through this self-task intended to update the guidance for the preparation of dossiers for sensory additives. In the preparation of this guidance, recent technological progress and scientific development, and the practical experience of the Panel have been taken into account.

The proposed modifications were initially discussed during the November Plenary. The guidance was adopted.[6]

- **Update of the "Guidance for the preparation of dossiers by categories of feed additives**

[4] http://www.efsa.europa.eu/en/efsajournal/pub/2527.htm
[5] http://www.efsa.europa.eu/en/efsajournal/pub/2532.htm
[6] http://www.efsa.europa.eu/en/efsajournal/pub/2534.htm

– Nutritional additives" (EFSA-Q-2010-01158)

The Rapporteur presented the question. The Panel through this self-task intended to update the guidance for the preparation of dossiers for nutritional additives. In the preparation of this guidance, recent technological progress and scientific development, and the practical experience of the Panel have been taken into account.

The proposed modifications were initially discussed during the November Plenary. The guidance was adopted.[7]

- **Update of the "Guidance for the preparation of dossiers by categories of feed additives – Zootechnical additives" (EFSA-Q-2010-01159)**

  The Rapporteur presented the question. The Panel through this self-task intended to update the guidance for the preparation of dossiers for zootechnical additives. In the preparation of this guidance, recent technological progress and scientific development, and the practical experience of the Panel have been taken into account.

  The proposed modifications were discussed and agreed. The guidance was adopted.[8]

- **Update of the "Guidance on consumer safety" (EFSA-Q-2010-01161)**

  The Rapporteur presented the question. The Panel through this self-task intended to update the guidance on consumer safety. In the preparation of this guidance, recent technological progress and scientific development, and the practical experience of the Panel have been taken into account.

  The proposed modifications were discussed and agreed. The guidance was adopted.[9]

- **Update of the "Guidance on user safety" (EFSA-Q-2010-01162)**

  The Rapporteur presented the question. The Panel through this self-task intended to update the guidance on user safety. In the preparation of this guidance, recent technological progress and scientific development, and the practical experience of the Panel have been taken into account.

  The proposed modifications were discussed and agreed. The guidance was adopted.[10]

- **Update of the "Guidance on additives already authorised for use in food" (EFSA-Q-2011-01095)**

  The Rapporteur presented the question. The Panel through this self-task intended to update the guidance for the preparation of dossiers for additives already authorised for use in food. In the preparation of this guidance, recent technological progress and scientific development, and the practical experience of the Panel have been taken into account.

  The proposed modifications were discussed and agreed. The guidance was adopted.[11]

- **Actisaf Sc 47 (*Saccharomyces cerevisiae*) for rabbits for fattening and non food-producing rabbits (EFSA-Q-2010-00936)**

  The Rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4(1) and re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003 of the product Actisaf® Sc 47 (*Saccharomyces cerevisiae* CNCM I-4407) as

[7] http://www.efsa.europa.eu/en/efsajournal/pub/2535.htm
[8] http://www.efsa.europa.eu/en/efsajournal/pub/2536.htm
[9] http://www.efsa.europa.eu/en/efsajournal/pub/2537.htm
[10] http://www.efsa.europa.eu/en/efsajournal/pub/2539.htm
[11] http://www.efsa.europa.eu/en/efsajournal/pub/2538.htm

zootechnical additive for rabbits for fattening and non food-producing rabbits

The draft opinion was initially discussed in the September Plenary. The FEEDAP Panel concluded that on the basis of the qualified presumption of safety approach that the product can be considered safe for the target species, for consumers of products derived from these food-producing species and the environment. Actisaf Sc47 is non irritant to skin. Given the absence of particles of inhalable size and the virtual absence of dust, exposure and therefore, toxicity and sensitisation via a respiratory route is not to be expected. Actisaf Sc47 showed the potential to reduce mortality in rabbits for fattening at a minimum dose of 5 x 10^9 CFU/kg feed. A similar effect can be expected in non food-producing rabbits.

The opinion was adopted.[12]

- **Quantum™ (6-phytase) for turkeys for fattening (EFSA-Q-2011-00148)**

The Chair of the WG presented the question and the draft opinion. This question refers to the modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of the product Quantum (6-phytase) as a feed additive for turkeys. The applicant is requesting a reduction of the minimum recommended dose.

The draft opinion was discussed. The FEEDAP Panel concluded that the additive at the proposed conditions of use has the potential to improve phosphorus utilisation in turkeys for fattening at the minimum dose of 500 FTU/kg.

The opinion was adopted.[13]

- **Potassium diformate for all animal species (EFSA-Q-2011-00422)**

A member of the WG presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003 of the product potassium diformate as a preservative for raw fish and fish by-products for feed use in all species.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species, the consumer and the environment when used under the proposed conditions It is considered an eye irritant. The Panel also concluded that the additive has the potential to increase the storage time of raw fish and fish by-products for feed use, in a dose dependent manner at low temperature.

The opinion was adopted.[14]

- ***Lactobacillus plantarum* Aber F1 (NCIMB 41028) and *Lactobacillus plantarum* L54 (NCIMB 30148) (EFSA-Q-2011-00943)**

The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2)/(7) of Regulation (EC) No 1831/2003 of the products *Lactobacillus plantarum* (NCIMB 41028) and *Lactobacillus plantarum* (NCIMB 30148) as silage additives for all species.

The draft opinion was discussed. The FEEDAP Panel concluded that both active agents fulfil the requirements of the qualified presumption of safety approach to safety assessment. Therefore the use of the strains in the production of silage is considered safe for the target

[12] http://www.efsa.europa.eu/en/efsajournal/pub/2531.htm
[13] http://www.efsa.europa.eu/en/efsajournal/pub/2533.htm
[14] http://www.efsa.europa.eu/en/efsajournal/pub/2530.htm

species, the consumer and the environment. The additives should be considered to have the potential to be skin and respiratory sensitisers. The FEEDAP Panel also concluded that both additives, each consisting of a single strain of *L. plantarum*, have the potential to improve the production of silage by increasing the preservation of dry matter and reducing the loss of protein. This was demonstrated in a range of easy, moderately difficult and difficult to ensile forage species.

The opinion was adopted.[15]

5.2. Discussion of the following scientific opinions

- **Methionine (7 forms) for all animal species (EFSA-Q-2010-00995)**

  Not discussed due to lack of time

- **Brown HT for cat and dogs (EFSA-Q-2010-01534)**

  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(2) of Regulation (EC) No 1831/2003 of the product Brown HT as a sensory additive for cats and dogs.

  An initial discussion took place. The opinion will be finalised once the additional information requested to the applicant will be received and evaluated.

- **L-Carnitine and L-carnitine L-tartrate for all animal species (EFSA-Q-2011-00251)**

  Not discussed due to lack of time

- **L-Carnitine for all animal species (EFSA-Q-2011-00252)**

  Not discussed due to lack of time

6. PROGRESS REPORT ON ONGOING WORK

Not discussed

7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

Not discussed

8. NEW REQUESTS TO EFSA

8.1. 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-2011-01170	VevoVitall® (Benzoic acid) for pigs for reproduction
EFSA-Q-2011-01171	Danisco Xylanase 40000G / Danisco Xylanase 40000 L (endo-1,4-beta-xylanase) for laying hens and all poultry minor species
EFSA-Q-2011-01172	RONOZYME® HiPhos (GT) (6-phytase) for poultry and pigs
EFSA-Q-2011-01234	Tocopherol-rich extracts of natural origin (E306), Tocopherol-rich extracts of natural origin / delta rich, Synthetic tocopherol (Tocopherol)for all animal species

[15] http://www.efsa.europa.eu/en/efsajournal/pub/2529.htm

EFSA-Q-2011-01235	Synthetic alpha-tocopherol for all animal species
EFSA-Q-2010-01525	Capsanthin for all poultry species, dogs and cats, ornamental fish and birds

8.2. 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-2010-01221	Lactic acid and calcium lactate for all animal species	24/11/2011
EFSA-Q-2010-01285	Chemically defined flavouring – Disodium 5'-ribonucleotides, Disodium 5'-guanylate (GMP), Disodium 5'-inosinate (IMP)for all animal species	14/11/2011
EFSA-Q-2010-01322	Inositol for all animal species	18/11/2011
EFSA-Q-2011-00330	Cobalt E 3 // Cobalt (cobaltous acetate tetrahydrate, basic cobaltous carbonate monohydrate and cobaltous sulphate heptahydrate) for all animal species	16/11/2011
EFSA-Q-2011-00331	Cobalt E 3 // Basic cobaltous carbonate monohydrate (film granulated preparation)for all animal species	16/11/2011
EFSA-Q-2011-00332	Cobalt E 3 // Cobalt carbonate for Ruminants, horses and rabbits	16/11/2011
EFSA-Q-2011-00744	Iodine E 2 // Calcium iodate, anhydrous and potassium iodide for all animal species	08/12/2011
EFSA-Q-2011-00745	Iodine E 2 // Calcium iodate, anhydrous for all animal species	08/12/2011
EFSA-Q-2011-00746	Iodine E 2 // Calcium iodate, anhydrous and potassium iodide for all animal species	08/12/2011
EFSA-Q-2011-00747	Iodine E 2 // Calcium iodate, anhydrous (film granulated preparation) for all animal species	08/12/2011
EFSA-Q-2011-00766	Shellac for all animal species	01/12/2011
EFSA-Q-2011-00849	Powdered cellulose for all animal species	01/12/2011
EFSA-Q-2011-00946	L-trytophan and related compounds // L-tryptophan for all animal species	24/11/2011
EFSA-Q-2011-00947	L-trytophan and related compounds // L-tryptophan technically pure for all animal species	24/11/2011
EFSA-Q-2011-00948	L-trytophan and related compounds // L-tryptophan, technically pure for all animal species	24/11/2011
EFSA-Q-2011-00949	L-trytophan and related compounds // L-tryptophan, technically pure for all animal species	24/11/2011
EFSA-Q-2011-00991	L-lysine and related compounds // Lysine (Concentrated liquid L-lysine (base), L-lysine monohydrochloride, technically pure, L-lysine sulphate produced by fermentation with Corynebacterium glutamicum (solid form and liquid form)) for all animal species	24/11/2011
EFSA-Q-2011-00992	L-lysine and related compounds // Concentrated liquid L-lysine (base) for all animal species	24/11/2011
EFSA-Q-2011-00993	L-lysine and related compounds // Concentrated liquid L-lysine-monohydrochloride for all animal species	24/11/2011
EFSA-Q-2011-00994	L-lysine and related compounds // L-lysine-monohydrochloride, technically pure for all animal species	24/11/2011

EFSA-Q-2011-00995	L-lysine and related compounds // L-lysine (L-lysine monohydrochloride and L-lysine sulphate) for all animal species	24/11/2011
EFSA-Q-2011-00996	L-lysine and related compounds // L-lysine (L-lysine monohydrochloride and L-lysine sulphate) for all animal species	24/11/2011

8.3. Selftasks

EFSA-Q-Number	Subject
EFSA-Q-2011-01173	Technical guidance on the safety of use of *Enterococcus faecium* in animal nutrition

9. GENERAL INFORMATION FROM EFSA

Not discussed.

10. EMERGING RISKS

Not discussed.

11. MISCELLANEOUS

Marina Marini, from the European Commission informed the Panel about the regulatory follow-up of the opinions adopted during the current mandate of the Panel.