DRAFT MINUTES OF THE 73RD PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (FEEDAP)

(PARMA, 7-9 DECEMBER 2010)

(AGREED ON 1 FEBRUARY 2011)

PARTICIPANTS

Panel Members
Gabriele Aquilina, Georges Bories, Paul Brantom, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Noël Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Reinhard Kroker, Lubomir Leng, Ingrid Halle (1st day), Alberto Mantovani, Miklós Mézes, Derek Renshaw and Maria Saarela.

Apologies
Ingrid Halle (2nd and 3rd days), Anne-Katrine Lundebye Haldorsen.

EFSA
Claudia Roncancio-Peña, Montserrat Anguita, Rosella Brozzi, Matteo Lorenzo Innocenti, Maria Vittoria Vettori, Nicola Jane Reynolds.

European Commission
Marta Ponghellini (DG SANCO) and Christoph von Holst (DG JRC, 2nd day).

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 73rd Plenary meeting of the FEEDAP Panel.

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

2. ADOPTION OF THE AGENDA

The agenda was adopted after the removal of Fresta® F (Carvone) for weaned piglets (EFSA-Q-2009-00939). The Working Group has identified several information, necessary to conclude on the safety and efficacy of the additive, which require a clarification from the applicant. A letter informing the applicant will be sent in the next days.

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. For further details on the outcome of the screening of the ADoI and SDoI, please refer to the Annex.

4. ADOPTION OF THE DRAFT MINUTES OF THE 72ND PLENARY MEETING

The minutes of the 72nd Plenary meeting of the Panel held on 9-11 November 2010 were reviewed and agreed.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Cygro 10G (maduramicin ammonium) for chickens for fattening (EFSA-Q-2008-750)**

  The Rapporteurs of the Working Group presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety and efficacy of Cygro® 10G (maduramicin ammonium α) as coccidiostat for chickens for fattening.

  The draft opinion was discussed. The Panel concluded that Cygro® 10G at the use level of 5-6 mg maduramicin/kg complete feed is effective in controlling coccidiosis in chickens for fattening. The highest proposed dose (6 mg/kg) appears near to intolerance level of chickens for fattening. Maduramicin ammonium α at the maximum dose of 6 mg/kg feed is considered safe for the consumers and the environment. With regard to the user safety the Panel concluded that any direct dermal contact with the additive must be avoided and inhalation should be minimised. A series of recommendations were also made.

  The opinion was adopted.[2]

- **Cygro 10G (maduramicin ammonium) for turkeys (EFSA-Q-2008-757)**

  The Rapporteur of the WG presented the question and the draft opinion. This question refers to an application for the modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of the product Cygro® 10G (maduramicin ammonium α) for turkeys for fattening. The applicant is seeking authorisation for a new formulation which contains the same concentration of active substance and will be used under the same conditions as specified for Cygro 1%. Cygro® 10G differs only in the excipients used.

  The draft opinion was discussed. The Panel concluded that the new formulation does not adversely influence the stability of maduramicin ammonium α and that the use of the new formulation would not be expected to introduce any additional concerns for the safety of turkeys, consumers of turkey products, for those handling the product or for the environment. Evidence has shown that the new formulation is effective in the control of Eimeria infections in chickens for fattenning at the use dose level.

  The opinion was adopted.[3]

- **Avizyme® 1505 (endo-1-4-beta-xylanase, subtilisin and alpha-amylase) for laying hens (EFSA-Q-2009-00470)**

  The Rapporteur presented the question and the draft opinion. This question refers to an application under Article 4 of Regulation (EC) No 1831/2003 of the product Avizyme® 1505 (endo-1-4-beta-xylanase, subtilisin and alpha-amylase) as zootechnical additive for use in laying hens.

  The draft opinion was reviewed. The safety aspects other than safety for the target species have already been considered in two previous opinions on the same product. Only safety and efficacy for laying hens were considered in the opinion. The Panel concluded that the

[1] http://www.efsa.europa.eu/en/events/event/feedap101109-m.pdf
[2] http://www.efsa.europa.eu/en/efsajournal/pub/1952.htm
[3] http://www.efsa.europa.eu/en/efsajournal/pub/1954.htm

additive is safe and efficacious for the target species. However the Panel noted that the analysed concentrations for amylase were about 5 times higher than the intended values.

The opinion was adopted.[4]

- **Taminizer D (dimethylglycine sodium salt) for chickens for fattening (EFSA-Q-2009-00881)**

  The Rapporteur presented the question and the draft opinion. This question refers to an application under Article 4 of Regulation (EC) No 1831/2003 of the product Taminizer D (dimethylglycine sodium salt) as zootechnical additive for use in chickens for fattening.

  The draft opinion was reviewed. The Panel concluded that the additive is safe for the target species, the consumer and the environment when used at the recommended use levels. Taminizer D is not a skin irritant but may be an eye irritant. In the absence of data to the contrary, dimethylglycine sodium salt should be considered as a skin sensitiser. The Panel also concluded that Taminizer has the potential to increase the performance of chickens for fattening and an impact on product quality is unlikely.

  The opinion was adopted.[5]

- **Miya-Gold® (*Clostridium butyricum*) for weaned piglets, minor porcine and minor avian species (EFSA-Q-2010-00140)**

  The Rapporteur presented the question and the draft opinion. This question refers to an application under Article 4 of Regulation (EC) No 1831/2003 of the product Miya-Gold® EU (*Clostridium butyricum*) as zootechnical additive for use in weaned piglets, minor weaned porcine species and minor avian species. Furthermore, this question also refers to an application for the modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of the product Miya-Gold® (*Clostridium butyricum*) to include a more concentrated formulation (Miya-Gold®EU) and to change the strain designation (from FERM-P No 1476 to FERM-BP 2789).

  The draft opinion was reviewed. The Panel concluded that the product is safe for weaned piglets and pigs for fattening and, given the high margin of safety demonstrated in the tolerance study and the similar proposed conditions of use, the additive can be also considered safe for minor porcine species. The safety for minor avian species can be extrapolated from the already assessed safety studies for chickens for fattening at the same proposed conditions of use. The product has been considered efficacious for weaned piglets, minor weaned porcine species, and minor avian species, but excluding laying birds. Use of the more concentrated formulation Miya-Gold®EU is not expected to introduce hazards for consumers or the environment not already considered in the previous application or for the target species. However, the large proportion of particles with a diameter of less than 10 µm found in Miya-Gold®EU may increase the likelihood for respiratory sensitisation of users of the additive. The Panel also recommended that the EU authorisation for Miya-Gold® in all of its formulations should be for *Clostridium butyricum* FERM-BP 2789.

  The opinion was adopted.[6]

- **BioPlus® 2B (*Bacillus licheniformis* and *Bacillus subtilis*) for turkeys for fattening – compatibility with semduramycin sodium and formic acid) (EFSA-Q-2010-01027)**

  The Chair of the Panel presented the question and the draft opinion that has been already

[4] http://www.efsa.europa.eu/en/efsajournal/pub/1949.htm
[5] http://www.efsa.europa.eu/en/efsajournal/pub/1950.htm
[6] http://www.efsa.europa.eu/en/efsajournal/pub/1951.htm

pre-discussed in the 72nd Plenary meeting of the FEEDAP Panel. This question refers to an application for the modification of the terms of authorisation of the product BioPlus 2B for turkeys for fattening to allow its use in feeds containing semduramycin sodium and formic acid.

The draft opinion was reviewed. The Panel concluded that the use of the product is compatible with semduramycin sodium and formic acid.

The opinion was adopted.[7]

- **Comments by the Austrian delegation on the scientific opinion on the product Cylactin® (*Enterococcus faecium*) as a feed additive for chickens for fattening (EFSA-Q-2010-01264)**

  The Rapporteur presented the question and the draft opinion. The Panel was requested by the EC to evaluate the comments made by the Austrian delegation concerning the safety of Cylactin® (*Enterococcus faecium* NCIMB 10415), in particular as regards the resistance to kanamycin.

  The draft opinion was reviewed. The Panel agreed with the general points raised in the paragraphs 1, 3, 4, 5 and 6 of the letter from the Austrian Agency for Health and Food Safety (AGES). The Panel also provided specific and detailed answers to the other issues (paragraphs 2, 7 and 8) raised by AGES, reiterating the conclusions reached in its previous opinion on the safety and efficacy of Cylactin® as a feed additive for chickens for fattening.

  The statement was adopted.[8]

- **Statement on the use of feed additives via water (EFSA-Q-2010-01272)**

  The Rapporteur presented the question and the draft opinion. This question refers to a self task of the Panel to assess the use of feed additives authorised/applied for use in feed when supplied via water.

  The draft opinion was reviewed. The Panel concluded that, given that the animal exposure to an additive is the same and excluding (i) technological additives which exert their effects on feed, (ii) additives for which a maximum content is set by authorisation and (iii) additives for fish, there is no need to assess separately safety and efficacy of additives administered via water when an authorisation/application for use in feed exists.

  The statement was adopted.[9]

5.2. Discussion of the following scientific opinions

- **Cycostat 66G (robenidine hydrochloride) for rabbits for breeding and fattening purposes (EFSA-Q-2008-752)**

  The Rapporteurs from the Working Group presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety and efficacy of Cycostat® 66G (robenidine hydrochloride) as coccidiostat for rabbits for breeding and fattening purposes.

  The draft opinion was discussed, focussing on the characterisation of the additive and the safety for the target species. Due to lack of time, the discussion could not be completed. The remaining part of the opinion will be discussed at the next plenary meeting.

- **Sel-Plex (organic form of selenium produced by Saccharomyces cerevisiae) for all**

[7] http://www.efsa.europa.eu/en/efsajournal/pub/1953.htm
[8] http://www.efsa.europa.eu/en/efsajournal/pub/1955.htm
[9] http://www.efsa.europa.eu/en/efsajournal/pub/1956.htm

animal species (EFSA-Q-2009-00752)

Not discussed due to lack of time.

- **Technical Guidance document for the assessment of additives intended to be used in pets and other non food-producing animals (EFSA-Q-2010-01226)**

  Not discussed due to lack of time.

- **Bentonite (dioctahedral montmorillonite) (Mycofix® Secure) for all animal species (EFSA-Q-2010-00770)**

  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, and are currently being checked for completeness:

Additive	EFSA-Q-Number
Polyoxyethylene (20) sorbitan monooleate for all animal species	EFSA-Q-2010-01222
Iron oxide yellow for all animal species	EFSA-Q-2010-01274
L-carnitine and L-carnitine L-tartrate for all animal species	EFSA-Q-2010-01275
Lactobacillus buchneri DSM 22963 for all animal species	EFSA-Q-2010-01276
Vitamin D3 (cholecalciferol) for all animal species	EFSA-Q-2010-01277
Vitamin D3 (cholecalciferol) for in 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-2010-01278
Sorbic acid and potassium sorbate for all animal species	EFSA-Q-2010-01279
Folic acid for all animal species	EFSA-Q-2010-01280
Potassium sorbate (Nutrinova® Potassium Sorbate Powder and Nutrinova® Potassium Sorbate Granules) for all animal species	EFSA-Q-2010-01281
Botanically defined flavourings from BDG 07 - Geraniales, myrtales, poales for all animal species and categories	EFSA-Q-2010-01282
Lignosulphonate for all animal species	EFSA-Q-2010-01283
L-cysteine hydrochloride monohydrate for pets	EFSA-Q-2010-01284

Chemically defined flavouring - Disodium guanosine 5'-monophosphate (GMP) for all animal species and categories	EFSA-Q-2010-01285
Botanically defined flavourings from BDG 02 - Apiales and austrobaileyales for all animal species and categories	EFSA-Q-2010-01286
ROVABIO® EXCEL (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase) for chickens for fattening, laying hens, turkeys for fattening, piglets (weaned), pigs for fattening, ducks, guinea fowls, quails, geese, pheasants, pigeons	EFSA-Q-2010-01287
Betaine anhydrous for all animal species	EFSA-Q-2010-01288
Origanum heracleoticum L. for suckling piglets, weaned piglets, pigs for fattening, sows for reproduction, sows for benefits in piglets, chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening and breading and reared for breeding, calves for rearing, veal production, cattle for fattening, dairy cows for milk production, cows for reproduction, lambs for rearing, lambs for fattening, dairy sheep for milk production, ewes for reproduction, kids for rearing, kids for fattening, dairy goats for milk production, goats for reproduction, fin fish, shrimps	EFSA-Q-2010-01289
Vitamin C (L-ascorbic acid and ascorbyl monophosphate calcium sodium salt) for all animal species	EFSA-Q-2010-01290
Iron oxide black for all animal species	EFSA-Q-2010-01291
Iron oxide red for all animal species	EFSA-Q-2010-01292
Botanically defined flavourings from BDG 09 - Zingiberales for all animal species and categories	EFSA-Q-2010-01293
Vitamin A (retinol acetate, retinol palmitate, retinol propionate) for all animal species	EFSA-Q-2010-01294
KEMZYME Plus Liquid (endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, alpha-amylase and endo-1,4-beta-xylanase) for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, ducks for fattening/laying, turkeys for laying, quails, pheasants, partridges, guinea fowl, geese for fattening/laying, pigeons, ostriches, peacocks, flamingos, ornamental birds, piglets (weaned)	EFSA-Q-2010-01295
Botanically defined flavourings from Botanical Group 06 - Laurales, magnoliales, piperales for all animal species and categories	EFSA-Q-2010-01296
KEMZYME Plus Dry (endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, alpha-amylase, bacillolysin and endo-1,4-beta-xylanase) for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, ducks for fattening/laying, turkeys for laying, quails, pheasants, partridges, guinea fowl, geese for	EFSA-Q-2010-01297

fattening/laying, pigeons, ostriches, peacocks, flamingos, ornamental birds, piglets (weaned)	
Belfeed B MP/ML (endo-1,4-beta-xylanase) for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys for breeding purposes, turkeys reared for breeding, ducks, piglets (weaned), pigs for fattening, minor poultry species for fattening and laying	EFSA-Q-2010-01298
Taurine for all animal species	EFSA-Q-2010-01299
Ethyl ester of beta-apo-8'-carotenoic acid for poultry for fattening and poultry for laying	EFSA-Q-2010-01300
L-lysine (L-lysine monohydrochloride and L-lysine sulphate) for all animal species	EFSA-Q-2010-01301
Propionic acid, sodium propionate, calcium propionate and ammonium propionate for all animal species	EFSA-Q-2010-01302
Cobalt (cobaltous acetate tetrahydrate, basic cobaltous carbonate monohydrate and cobaltous sulphate heptahydrate) for all animal species	EFSA-Q-2010-01303
Lactobacillus brevis DSMZ 21982 for all animal species	EFSA-Q-2010-01304
L-threonine, tecnically pure for all animal species	EFSA-Q-2010-01305
L-tryptophan, tecnically pure for all animal species	EFSA-Q-2010-01306
Botanically defined flavourings from BDG 01 - Lamiales for all animal species and categories	EFSA-Q-2010-01307
Sorbic acid (Nutrinova® Sorbic Acid) for all animal species	EFSA-Q-2010-01308
Formaldehyde for all animal species	EFSA-Q-2010-01309
L-tryptophan, technically pure for all animal species	EFSA-Q-2010-01310
Melissa officinalis dry extract (Nor-Balm®) for all animal species	EFSA-Q-2010-01311
L-tyrosine (L-tyrosine - food grade) for all animal species	EFSA-Q-2010-01312
L-cystine for all animal species	EFSA-Q-2010-01313
L-threonine, technically pure for all animal species	EFSA-Q-2010-01314
Methionine-zinc, technically pure for all animal species	EFSA-Q-2010-01315
D-(+)-biotin for all animal species	EFSA-Q-2010-01316
Iodine (calcium iodate and potassium iodide) for all animal species	EFSA-Q-2010-01317
Nicotinamide for all animal species	EFSA-Q-2010-01318
Vitamin B2 (riboflavin and riboflavin 5'-phosphate ester monosodium salt) (Riboflavin Universal; ROVIMIX® B2 80-SD; Riboflavin 5'- Phosphate Sodium) for all animal species	EFSA-Q-2010-01319

Vitamin C (L-ascorbic acid, sodium L-ascorbate, calcium L-ascorbate, 6-palmityl L-ascorbic acid, ascorbyl monophosphate calcium sodium salt) for all animal species	EFSA-Q-2010-01320
Botanically defined flavourings from BDG 10 - Dipsacales for all animal species and categories	EFSA-Q-2010-01321
Inositol for all animal species	EFSA-Q-2010-01322

8.2. Self-tasks

Subject	EFSA-Q-Number
Statement on the use of feed additives via water	EFSA-Q-2010-01272

8.3. Other mandates

Subject	EFSA-Q-Number
Public consultation on the Guidance for the assessment of biomasses for use in animal nutrition	EFSA-Q-2010-01263
Comments by the Austrian delegation on the scientific opinion on the product Cylactin (*Enterococcus faecium*) as a feed additive for chickens for fattening (Art. 31)	EFSA-Q-2010-01264

8.4. Valid applications under Regulation (EC) No 1831/2003 since the previous meeting

Applications considered valid for the start of the assessment:

#	Additive	EFSA-Q-Number	Valid on
1	Xylanase (endo-1,4-beta-xylanase) for turkeys	EFSA-Q-2008-288	19/11/2010
2	Lysine for all animal species	EFSA-Q-2010-01036	17/11/2010
3	CRINA® Poultry Plus (benzoic acid and essential oil compounds) for chickens for fattening	EFSA-Q-2010-01130	16/11/2010
4	GalliPro® (*Bacillus subtilis*) for chickens for fattening	EFSA-Q-2010-01151	01/12/2010
5	*Lactobacillus plantarum* DSM 21762 for all animal species	EFSA-Q-2010-01164	08/11/2010
6	Vitamin K3 (menadione sodium bisulphite and menadione nicotinamide bisulphite) for all animal species	EFSA-Q-2010-01167	11/11/2010
7	Chemically defined flavourings from Chemical Group 13 - Furanones and tetrahydro-furfuryl derivates for all animal species and categories	EFSA-Q-2010-01169	12/11/2010

8	Chemically defined flavourings from Flavouring Group 34 - Aminoacids for all animal species and categories	EFSA-Q-2010-01170	12/11/2010
9	Chemically defined flavourings from Flavouring Group 28 - Pyridine, pyrrole and quinoline derivatives for all animal species and categories	EFSA-Q-2010-01171	12/11/2010
10	Chemically defined flavourings from Flavouring Group 09 - Primary aliphatic saturated or unsaturated alcohols/aldehydes/acids/acetals/esters with a second primary, secondary or tertiary oxygenated functional group including aliphatic lactones for all animal species and categories	EFSA-Q-2010-01177	24/11/2010
11	Urea, technically pure for ruminants from the beginning of rumination	EFSA-Q-2010-01178	18/11/2010
12	Chemically defined flavouring - Glycyrrhizic acid, ammoniated for all animal species and categories	EFSA-Q-2010-01179	12/11/2010
13	Chemically defined flavourings from Flavouring Group 29 - Thiazoles, thiophene, thiazoline and thienyl derivatives for all animal species and categories	EFSA-Q-2010-01180	18/11/2010
14	Chemically defined flavourings from Flavouring Group 08 - Secondary alicyclic saturated and unsaturated alcohols/ketones/ketals/esters/ with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols for all animal species and categories	EFSA-Q-2010-01181	24/11/2010
15	Chemically defined flavourings from Flavouring Group 14 - Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms for all animal species and categories	EFSA-Q-2010-01218	01/12/2010
16	Chemically defined flavourings from Flavouring Group 03 - Alfa, beta-unsaturated (alkene or alkyne) straight-chain and branched-chain aliphatic primary alcohols/aldehydes/acids, acetals and esters with esters containing alfa, beta-unsaturated alcohol and acetal containing alfa, beta-unsaturated alcohols or aldehydes for all animal species and categories	EFSA-Q-2010-01219	01/12/2010
17	Chemically defined flavouring - Naringin for all animal species	EFSA-Q-2010-01220	29/11/2010
18	Chemically defined flavouring - Thaumatin for all animal species	EFSA-Q-2010-01223	30/11/2010

19	Ethoxyquin (6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline) for all animal species	EFSA-Q-2010-01224	01/12/2010

9. GENERAL INFORMATION FROM EFSA

Not discussed.

10. EMERGING RISKS

Not discussed.

11. MISCELLANEOUS

- Riitta Maijala, Director of Risk Assessment Directorate, Dirk Detken, Head of Unit of Legal & Policy Department, and Simone Gabbi, Legal Officer, participated to the meeting to discuss on issues related with the policy on the Declaration of Interest.

Annex

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF THE ANNUAL DECLARATION OF INTERESTS (ADoI)

- In his ADoI Dr. Paul Brantom declared a past consultancy with Danisco (Avizyme® 1505). In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest. Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest, the said expert incurs in the limitations identified under point C.III.b that is, he may address orally or in writing questions raised during the discussion of products, but cannot draft opinions or parts of them.
- In her ADoI, Dr Maria Saarela declared the following interest: the Institute where she works performed some research activities related to a competitor of the product Cylactin (*Enterococcus faecium*). In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest. Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest, the said expert incurs in the limitations identified under point C.III.b that is, she may address orally or in writing questions raised during the discussion of products, but cannot draft opinions or parts of them.