DRAFT MINUTES OF THE 74TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (FEEDAP)

(PARMA, 1-3 FEBRUARY 2011)

(AGREED ON 15 MARCH 2011)

PARTICIPANTS

Panel Members

Gabriele Aquilina, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Noël Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle(1st and 2nd day), Reinhard Kroker, Lubomir Leng, Anne-Katrine Lundebye Haldorsen (1st and 2nd day), Alberto Mantovani, Miklós Mézes, Derek Renshaw and Maria Saarela (1st and 2nd day).

Apologies

Paul Brantom, Ingrid Halle (3rd day), Anne-Katrine Lundebye Haldorsen (3rd day), Maria Saarela (3rd day).

EFSA

Claudia Roncancio-Peña, Montserrat Anguita, Matteo Lorenzo Innocenti, Gloria Lopez-Galvez, Maria Vittoria Vettori, Lucilla Gregoretti, Jaume Galobart and 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 addition of Coxidin (monensin sodium) for chickens for fattening and turkeys (EFSA-Q-2010-000915)

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 73RD PLENARY MEETING

The minutes of the 73rd Plenary meeting of the Panel held on 7-9 December 2010 were reviewed and agreed.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

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

  This statement was adopted by the Panel on December 2010. However, after its adoption it was identified that it would be useful to include a detailed the recommendation made and include an annex. The annex lists those feed additives for which the FEEDAP Panel considers that use in water for drinking does not represent an additional risk to use in feed.

  The statement was adopted.[2]

- **Protural (sodium benzoate) for piglets (EFSA-Q-2009-00446)**

  The Rapporteur of the WG 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 Protural (sodium benzoate) as zootechnical additive for use in weaned piglets.

  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. Protural is not considered a skin and eye irritant. In the absence of data to the contrary, sodium benzoate should be considered as a skin sensitizer. The Panel concluded that Protural has the potential to improve performance in weaned piglets.

  The opinion was adopted.[3]

- **Danisco Xylanase G and L (endo-1,4-beta-xylanase) for weaned piglets and pigs for fattening (EFSA-Q-2009-00802)**

  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 Danisco Xylanase G and L (endo-1,4-beta-xylanase) as zootechnical additive for use in weaned piglets and pigs for fattening. The efficacy and safety of the additive for chickens for fattening, laying hens, ducks for fattening and turkeys, including the safety for the consumer, the user and the environment as well as the safety aspects of the genetic modification, have already been assessed by EFSA.

  The draft opinion was reviewed. The application refers to two different formulations of the additive; in terms of tolerance and efficacy the formulations are considered equivalent when used at the same dose. The Panel concluded that the additive is safe for the target species when used at the maximum recommended dose. Based on the trials provided, covering from weaning of piglets to slaughter of pigs, it was concluded that Danisco Xylanase is efficacious in improving the performance of piglets and pigs for fattening.

  The opinion was adopted.[4]

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

[1] http://www.efsa.europa.eu/en/events/event/feedap101207-m.pdf
[2] http://www.efsa.europa.eu/en/efsajournal/pub/1956.htm
[3] http://www.efsa.europa.eu/en/efsajournal/pub/2005.htm
[4] http://www.efsa.europa.eu/en/efsajournal/pub/2008.htm

The Rapporteurs from the Working Group presented the question and the draft opinion. This question refers to an application under Article 10(2) of Regulation (EC) No 1831/2003 of the product Cycostat® 66G (robenidine hydrochloride) as coccidiostat for rabbits for breeding and fattening purposes.

The discussion of the draft opinion already started during the 73rd Plenary meeting, focussing on the characterisation of the additive and the safety for the target species. The discussion continue during this plenary. The Panel concluded that feed concentrations ≤ 66 mg robenidine hydrochloride from Cycostat® 66G/kg complete feed are safe for breeding does. The margin of safety is about three. This conclusion can be extrapolated to rabbits for fattening. The product is safe for the consumer and the environment. Robenidine hydrochloride is not a skin or eye irritant and not a skin sensitiser. Robenidine hydrochloride at 50 mg robenidine hydrochloride/kg and 66 mg/kg feed has a potential to control coccidiosis in breeding does and rabbits for fattening, respectively.

- The opinion was adopted.[5,6]

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

  The Rapporteur presented the question and the draft opinion. This request refers to a self-task of the Panel for the assessment of additives intended for use in pets and other non food-producing animals.

  The draft guidance was discussed. This document details the requirements that Panel considers necessary for the assessment of the safety and efficacy of feed additives intended for use in pets and other non food-producing animals.

  The guidance was adopted.[7]

- **Coxidin® (monensin sodium) for chickens for fattening and turkeys (EFSA-Q-2009-00915)**

  The Rapporteur presented the question and the draft opinion. This question refers to an application under Article 13(3) of Regulation (EC) No 1831/2003 of the product Coxidin® (monensin sodium) as coccidiostat for chickens for fattening and turkeys. The efficacy and safety of the additive have already been assessed by EFSA in 2005 and 2006.

  The draft opinion was reviewed. The request of modification of the authorisation refers to a change in the composition of the existing product Coxidin® (monensin sodium), particularly to the replacement of wheat bran carrier with calcium carbonate. The Panel concluded that there is no reason to suppose that the proposed change in carrier would, in itself, constitute a hazard or alter the exposure of target species directly and consumers indirectly to the active substance. The change of the formulation is not expected to alter the risk for the environment. In the absence of data to the contrary, the additive should be considered as an eye irritant. Given the dustiness of the new formulation, the amount of potentially respirable particle and the concentration of monensin sodium in the dust, protective measures should be taken to avoid inhalation exposure. The Panel also concluded

[5] After the adoption of the opinion and following the provisions set in Article 8(5) of Regulation 1831/2003, EFSA forwarded without delay the final document to the applicant.
A mistake in the final calculation of the consumer safety assessment was identified. This was due to the unclear terminology used in the report of the tolerance study in rabbits. The applicant submitted an amendment to the final study report resolving the confusing terminology. The clarifications were taken into consideration and the opinion was modified accordingly. The modified document was adopted by the FEEDAP Panel on 7 March 2011 by written procedure.
[6] http://www.efsa.europa.eu/en/efsajournal/pub/2102.htm
[7] http://www.efsa.europa.eu/en/efsajournal/pub/2012.htm

that the new formulation is as effective as the authorised form in the control of *Eimeria* in chickens and turkeys for fattening.

The opinion was adopted.[8]

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

  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 Bentonite (dioctahedral montmorillonite) as technological additive, functional group: substances for the reduction of contamination of feed with mycotoxins, for use in all animal species.

  The draft opinion was reviewed. The Panel considers 0.5% bentonite as safe for all target species. The product is safe for the consumer and the environment. Bentonite is not irritant to skin and mildly irritant to eyes. Given the particle size distribution and high dusting potential of the additive, it is recommended that appropriate protection measures are taken to reduce exposure of workers/users via inhalation. The Panel also concluded that Bentonite with a minimum binding capacity of 100 mg aflatoxin per g bentonite has the potential to be efficacious as an aflatoxin binder in dairy cows, and that this conclusion can be extended to all ruminants. However, due to the lack of appropriate studies, the FEEDAP Panel is not in a position to assess the efficacy of the bentonite under application as an aflatoxin binder in any other species than ruminants.

  The opinion was adopted.[9]

- **AveMix® 02 CS and L (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase and polygalacturonase) for piglets (EFSA-Q-2011-00035)**

  The Rapporteur of the WG presented the question and the draft opinion. The FEEDAP Panel has been requested to deliver an opinion on the efficacy of AveMix® 02 CS and L (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase and polygalacturonase) for weaned piglets. In a previous opinion, the safety of the product for the target species, the consumer, the user and the environment was established. However, only one trial showed significant improvement in performance parameters at the recommended dose and therefore the Panel could not conclude on the efficacy of this enzyme preparation for piglets. The applicant has now provided two new efficacy studies.

  The draft opinion was reviewed. The Panel concluded that the additive has the potential to be efficacious at the recommended dose.

  The opinion was adopted.[10]

- **Evaluation of the safety of Hemp as animal feed (EFSA-Q-2010-00016)**

  The Rapporteurs presented the question and the draft opinion. The European Commission received a report from the Swiss authorities concerning the ban of the use of hemp as animal feed in Switzerland. The ban was based on an expert opinion which provided evidence on the fact that feeding hemp products to cows may result in milk having a concentration of delta-9-tetrahydrocannabinol (THC) that would exceed the maximum tolerable intake in certain consumer groups. It may not be excluded that THC transfer occurs also in other animal food products.

  The Panel was requested by the EC to evaluate the safety for the animals, the consumer and

[8] http://www.efsa.europa.eu/en/efsajournal/pub/2009.htm
[9] http://www.efsa.europa.eu/en/efsajournal/pub/2007.htm
[10] http://www.efsa.europa.eu/en/efsajournal/pub/2010.htm

the environment of feeding products of EU-authorised hemp varieties taking into account amongst others the background and the information submitted by the Swiss Authorities.

The draft opinion was reviewed. The Panel concluded, considering the nutritional properties of the hemp-derived products, that hemp seed and hemp seed cake could be used as feed material for all animal species and the whole hemp plant could be used in ruminants (and horses). No studies concerning tolerance or effects of graded levels of THC in food producing animals have been found in literature.

Based on a very limited number of studies performed in laboratory animals, farm animals and humans, following essentially single intravenous administration, oral or inhalation exposure to THC, it may be assumed that both the parent compound and its metabolites with psychoactive properties (especially 11-hydroxy-delta-9-THC) are distributed in the different tissues and organs, and excreted in milk. However, there is a lack of specific studies performed in food-producing species fed hemp products. Fat can be considered as a target tissue for THC exposure. The FEEDAP Panel adopted 0.15 % as transfer rate of oral THC to milk from dairy cows.

The provisional maximum tolerable daily intake (PMTDI) identified is 0.0004 mg/kg bw (corresponding to 0.024 mg for a 60-kg adult and 0.0048 mg for a 12-kg child), based on the LOEL (0,04 mg THC/kg) and applying a safety factor of 100. However, considering the results of a rat study with intra-peritoneal administration of THC where neuroendocrine effects were found at the lowest effective dose of 0.001 mg/kg bw, the Panel could not exclude an underestimation of the potential adverse effects, in particular for foetuses and new-borns.

Different exposure scenarios were considered for hemp plant-derived feed material, where the PMTDI will be exceeded in all cases. For seed-derived feed materials the resulting exposure of adults and children (one to three years old) was below the PMTDI in all scenarios. The conclusions drawn from milk consumption would in principle apply to other animal products.

The Panel concluded that there is not an option for the use of whole hemp plant derived feed materials in animal nutrition. In contrast, feeding hemp seed was considered safe for the consumer exposed to milk from dairy cows fed the feed material.

The Panel made some recommendations.

The opinion was adopted.[11]

5.2. Discussion of the following scientific opinions

- ***Lactobacillus buchneri* DSM 22963 for all animal species (EFSA-Q-2010-01276)**

  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 *Lactobacillus buchneri* DSM 22963 as technological additive (silage additive) for use in all animal species.

  The opinion will be submitted for adoption once the comments from the Member States are received and considered.

- **Sel-Plex (organic form of selenium produced by *Saccharomyces cerevisiae*) for all animal species (EFSA-Q-2009-00752)**

  Not discussed due to lack of time.

[11] http://www.efsa.europa.eu/en/efsajournal/pub/2011.htm

6. PROGRESS REPORT ON ONGOING WORK

- A meeting between the EC, EURL and EFSA to discuss on the general organisation and the workplan of the re-evaluation was held in Brussels on 12th -13th January 2011. The HoU informed the Panel on the issues discussed and the agreements reached during this meeting.
- The Panel was informed on comments received from the public consultation on Biomasses.

7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

- The Panel was informed about a public consultation on a draft guidance on risk assessment concerning potential risks arising from applications of nanoscience and nanotechnologies to food and feed. The deadline for the public consultation is the 25th February 2011

8. NEW REQUESTS TO EFSA

8.1. New applications under Regulation (EC) No 178/2002

The Commission has forwarded to EFSA the following new applications of feed additives seeking authorisation under Regulation (EC) No 178/2002 since the last Plenary meeting. These applications were presented to the Panel, who accepted them:

EFSA-Q-Number	Subject
EFSA-Q-2011-00035	AveMix® 02 CS and L (endo-1,3(4)-beta-glucanase, endo-1,4-beta-xylanase and pectinase) for piglets (weaned)

8.2. 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	Natugrain® TS/L (endo-1,4-beta-xylanase, endo-1,4-beta-glucanase) for chickens for rearing, turkeys for breeding purposes, turkeys reared for laying, minor avian species for fattening, minor avian species for laying, pet birds	EFSA-Q-2010-00937	25/01/2011
2	L-tryptophan for all animal species	EFSA-Q-2010-01026	03/01/2011
3	Selenomethionine (Selemax 1000 and Selemax 2000) for all animal species	EFSA-Q-2010-01029	06/12/2010
4	L-threonine for all animal species	EFSA-Q-2010-01034	03/01/2011
5	Di copper chloride tri hydroxide for all animal species	EFSA-Q-2010-01047	09/12/2010
6	L-threonine, technically pure for all animal species	EFSA-Q-2010-01067	14/12/2010
7	TOYOCERIN® (*Bacillus cereus* var. toyoi NCIMB 40112/CNCM I-1012) for calves for rearing	EFSA-Q-2010-01095	06/12/2010
8	*Bacillus subtilis* PB6 (*Bacillus subtilis* ATCC PTA-6737) for chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowls, pigeons, geese for fattening and ostriches	EFSA-Q-2010-01150	22/12/2010

9	Sodium saccharin for pigs, piglets (suckling and weaned), pigs for fattening, calves for rearing, calves for fattening	EFSA-Q-2010-01228	09/12/2010
10	Neohesperidine dihydrochalcone for piglets (suckling and weaned), pigs, pigs for fattening, bovines, calves for rearing up to 4 months and/or fattening up to 6 months, sheep, lambs for rearing up to 3 months, lambs for fattening up to 6 months or older, dairy sheep for milk production, fish, salmon and trout, dogs	EFSA-Q-2010-01229	09/12/2010
11	*Lactobacillus buchneri* DSM 22963 for all animal species	EFSA-Q-2010-01276	15/12/2010
12	Sorbic acid and potassium sorbate for all animal species	EFSA-Q-2010-01279	16/12/2010
13	Folic acid for all animal species	EFSA-Q-2010-01280	16/12/2010
14	Botanically defined flavourings from BDG 07 - Geraniales, myrtales, poales for all animal species and categories	EFSA-Q-2010-01282	21/12/2010
15	Lignosulphonate for all animal species	EFSA-Q-2010-01283	21/12/2010
16	Chemically defined flavouring - Disodium guanosine 5'-monophosphate (GMP) for all animal species and categories	EFSA-Q-2010-01285	21/12/2010
17	Betaine anhydrous for all animal species	EFSA-Q-2010-01288	21/12/2010
18	Vitamin C (L-ascorbic acid and ascorbyl monophosphate calcium sodium salt) for all animal species	EFSA-Q-2010-01290	03/01/2011
19	Botanically defined flavourings from Botanical Group 09 - Zingiberales for all animal species and categories	EFSA-Q-2010-01293	03/01/2011
20	Botanically defined flavourings from Botanical Group 06 - Laurales, magnoliales, piperales for all animal species and categories	EFSA-Q-2010-01296	03/01/2011
21	Taurine for all animal species	EFSA-Q-2010-01299	03/01/2011
22	Botanically defined flavourings from Botanical Group 01 - Lamiales for all animal species and categories	EFSA-Q-2010-01307	06/01/2011
23	Melissa officinalis dry extract (Nor-Balm®) for all animal species	EFSA-Q-2010-01311	07/01/2011
24	L-tyrosine (L-tyrosine - food grade) for all animal species	EFSA-Q-2010-01312	07/01/2011
25	L-cystine for all animal species	EFSA-Q-2010-01313	07/01/2011
26	Vitamin C (L-ascorbic acid, sodium L-ascorbate, calcium L-ascorbate, 6-palmityl L-ascorbic acid, ascorbyl monophosphate calcium sodium salt) for all animal	EFSA-Q-2010-01320	10/01/2011

9. GENERAL INFORMATION FROM EFSA

- A presentation was done to the Panel about the result of the FERA report on Terminology in Risk Assessments Used by the Scientific Panels and Scientific Committee of EFSA.

10. EMERGING RISKS

Not discussed.

11. MISCELLANEOUS

- The HoU confirmed that the 78th Plenary meeting (14th -16th June 2011) will be held in Berlin.
- The Panel was informed that the training on statistics has been cancelled. An internal training will be organised in the second half of the year.