MINUTES OF THE 42ND PLENARY MEETING

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

(PARMA, 18-19 SEPTEMBER 2007)

(ADOPTED ON 17 OCTOBER 2007)

PARTICIPANTS

Panel Members
Georges Bories, Paul Brantom, Andrew Chesson, Pier Sandro Cocconcelli, Bogdan Debski, Joop de Knecht, Noël Dierick, Anders Franklin, Jürgen Gropp, Ingrid Halle (1st day), Christer Hogstrand, Lubomir Leng, Anne Katrine Lundebye-Haldorsen, Alberto Mantovani, Miklós Mézes, Carlo Stefano Nebbia (2nd day), Walter Rambeck, Guido Rychen, Atte von Wright, Pieter Wester.

Apologies
Joaquim Brufau de Barberà, Ingrid Halle (2nd day), Carlo Stefano Nebbia (1st day).

EFSA
Claudia Roncancio-Peña, Jaume Galobart, Gloria López-Gálvez (scientific staff), Ketty Antonelli, (administrative staff).

European Commission
Taina Säteri (DG SANCO, by teleconference), Christoph von Holst (DG Joint Research Centre).

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 42nd 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 with the inclusion of the opinion on Kokcisan 120G for discussion and possible adoption.

3. DECLARATIONS OF INTEREST

Dr. Paul Brantom declared that he had provided consultancy services to Danisco regarding the dossier on Danisco Xylanase. Prof. Jürgen Gropp declared that he had provided consultancy services to Bayer regarding the dossier on Lantharenol® for cats. These experts were excluded from the discussion/adoption of the respective products. No other interests were declared relevant to the items of the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 41ST PLENARY MEETING ON 10-12 JULY 2007

The minutes of the 41st Plenary meeting of the Scientific Panel held on 10-12 July 2007 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of Calsporin® (*Bacillus subtilis*) for chickens for fattening (EFSA-Q-2007-040)**

  This question refers to the modification of an existing authorisation of a feed additive under Article 13(3) of Regulation (EC) No 1831/2003. The applicant is seeking to reduce the minimum dose from 1 x 10^9 cfu kg^{-1} to 0.5 x 10^9 cfu kg^{-1} complete feedingstuff.

  This opinion was already discussed during the Plenary meeting of April. At that time, the CRL report was not available. After reception and verification of the report, the opinion was presented to the Panel for possible adoption.

  The applicant has provided four efficacy trials plus a meta-analysis of these data that support the efficacy of the product at the lowest proposed dose. The Panel considers that the safety of the product would not be affected by the dose change.

  The opinion was adopted.[2]

- **Safety and efficacy of Natuphos® (3-phytase) for ducks for fattening (EFSA-Q-2007-041)**

  This question refers to a feed additive application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is asking for an extension of use of the product Natuphos®, which is a preparation of 3-phytase, as a zootechnical additive (functional group: digestibility enhancer) for ducks.

  This opinion was already discussed during the Plenary meeting of April. At that time, the CRL report was not available. After reception and verification of the report, the opinion was presented to the Panel for possible adoption.

  The efficacy of the product has been established for chickens for fattening and turkeys for fattening. The Panel considers that, since the mode of action of phytase in ducks is the same as in the major species, and based on the data provided by the balance trials, there is sufficient evidence to support the efficacy of Natuphos® in ducks at the minimum recommended dose (300 FTU kg^{-1} complete feed). The product is safe for ducks as shown by the tolerance study presented.

  The opinion was adopted.[3]

- **Efficacy of Coxidin® 25% (monensin sodium) for turkeys for fattening. (EFSA-Q-2007-067)**

[1] http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_41th_plenmeet.pdf
[2] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej543_calsporin_cff_50ppm_en,2.pdf
[3] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej544_natuphos_ducks_en,3.pdf

EFSA has been requested to deliver an opinion on the proposal made by the applicant for reducing the minimum content of monensin sodium from Coxidin® 25% in complete feedingstuffs for turkeys from the current 90 mg kg^{-1} to 60 mg kg^{-1}.

This opinion was already discussed during the Plenary of June. At that time, the CRL report was not available. After reception and verification of the report, the opinion was presented to the Panel for possible adoption.

On the basis of five floor pen studies submitted, the FEEDAP Panel concluded that 60 mg monensin sodium from Coxidin® kg^{-1} complete feed can be considered as the minimum effective dose in the control of turkey coccidiosis.

The opinion was adopted.[4]

- **Safety and efficacy of Lantharenol® (lanthanum carbonate octahydrate) for cats (EFSA-Q-2006-317)**

  This is an application under Article 4 of Regulation 1831/2003. The applicant is requesting authorisation of the product Lantharenol® to be used as zootechnical additive (functional group: other zootechnical additives) for adult cats to restrict the intestinal absorption of phosphorus.

  This opinion was already discussed during the previous Plenary meeting. However, the opinion was not adopted because the CRL report was not received. This has already been received now and has been verified by EFSA.

  The data provided showed that use of Lantharenol® can reduce the phosphorus absorption in adult cats at the lowest recommended dose. No negative effects were seen in the tolerance trials suggesting that Lantharenol® is safe for cats under the conditions of use proposed. However, any adverse effects that might occur over a life-long exposure to Lantharenol® would not be detected by the tolerance study. For this reason, the Panel recommended the establishment of a post-market monitoring plan able to recognise any long-term adverse effects. No concerns were raised for the owner/user or the environment.

  The opinion was adopted.[5]

- **Safety and efficacy of Ronozyme P (6-phytase) for ducks for fattening (EFSA-Q-2006-060)**

  The Rapporteur of the Working Group (WG) introduced the question and the draft opinion. This question refers to a feed additive application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Ronozyme P to be used as a zootechnical feed additive (functional group: digestibility enhancers and additives which favourably affect the environment) in ducks. This product is already authorised for chickens for fattening, turkeys for fattening, laying hens, piglets, pigs for fattening and sows, and provisionally authorised for salmonids.

  The Panel considers that there is enough evidence to support the efficacy of the product at the lowest recommended dose for ducks for fattening. The data on tolerance showed that the product is safe for the target species.

  The opinion was adopted after some editorial modifications.[6]

[4] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej545_coxidin_turkeys_en,0.pdf
[5] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178645767641.htm
[6] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej519_ronozymep_ducks_en,0.pdf

- **Safety and efficacy of Danisco Xylanase G/L (endo-1,4-beta-xylanase) for chickens for fattening, laying hens and ducks (EFSA-Q-2006-137)**

  The Rapporteur of the WG introduced the question and the draft opinion. This question refers to an application for authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Danisco Xylanase G/L as a zootechnical additive (functional group: digestibility enhancer) for chickens for fattening, laying hens and ducks for fattening. This enzyme preparation is produced by a genetically modified micro-organism, and the GMO Panel of EFSA has assessed the safety of the genetic modification (the GMO Panel adopted this opinion on 12 September 2007).

  The FEEDAP Panel considers that there is sufficient evidence to support the efficacy of the product for the three target species. However, insufficient evidence has been provided to justify the lowest recommended dose proposed by the applicant for chickens for fattening and laying hens. The Panel also considers that the product is safe for the target species, humans and the environment.

  The opinion was adopted after some editorial modifications.

- **Safety and efficacy of Panaferd-AX (red carotenoid-rich bacterium *Paracoccus carotinifaciens*) for salmon and trout (EFSA-Q-2006-173)**

  The Rapporteur of the WG introduced the question and the draft opinion. This question refers to an application for authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Panaferd-AX (astaxanthin-rich bacterium *Paracoccus carotinifaciens*) as a sensory additive (functional group: colourants) for salmon and trout.

  The discussion focussed on the identity of the product and its function as feed additive in relation to the three active compounds: astaxanthin, adonirubin and cantaxanthin. The Panel considered that there is sufficient evidence to support the efficacy and the safety of the product for animals, consumer/user and the environment. Adonirubin was assumed to shared toxicological properties with canthaxanthin. An ADI for the sum of cantaxanthin and adonirubin was therefore proposed.

  After some editorial modifications, the opinion was adopted.[7]

- **Update on the safety of Kokcisan 120 G (salinomicin sodium) for chickens for fattening (EFSA-Q-2007-099)**

  The Rapporteur of the WG introduced the question and the draft opinion. The FEEDAP Panel has already delivered two opinions on the safety of this product (2004[8] and 2006[9]), in which no conclusions could be reached on the safety for the consumer due to lack of data. New data has been provided by the applicant in the form of a chronic toxicity/carcinogenicity study and new residue data.

  The FEEDAP Panel has established an ADI of 0.005 mg SAL-Na from Kokcisan kg^{-1} bw day^{-1} (0.3 mg per 60 kg person and day). The theoretical exposure of the consumer has been calculated according to daily human food consumption values set by Directive 2001/79/EC. At 0.25-day, which corresponds to a practical zero withdrawal time, the consumer exposure (0.182 mg) would represent 61 % of the ADI. Therefore, no MRL would normally be

[7] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej546_panaferdax_slm_tt_en,0.pdf
[8] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/opinion18_feedap_ej63_kokcisan_en1,0.pdf
[9] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej378_kokcisan_2_en.pdf

required. However, if for practical reasons a withdrawal period should be established then MRLs applicable at one-day will be 0.005 mg kg^{-1} for liver, kidney and muscle and 0.015 mg kg^{-1} for skin/fat. Consumption of edible tissues containing residues at the MRLs would amount to 58 % of the ADI.

After some editorial modifications the opinion was adopted.[10]

- **Safety and efficacy of Toyocerin® (*Bacillus cereus*) for turkeys (EFSA-Q-2007-090)**

  The Rapporteur of the WG introduced the question and the draft opinion. This question refers to an application for authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Toyocerin® as a zootechnical additive for turkeys (functional group: gut flora stabilisers). This product is already permanently authorised for its use in piglets up to four months, pigs for fattening, sows from one week prior to farrowing until weaning, cattle for fattening, chickens for fattening and rabbits for fattening.

  Some discussion took place on the efficacy studies presented. The Panel considered that enough evidence has been provided to support the efficacy and the safety of the product for the target species.

  The opinion was adopted.[11]

- **Safety and efficacy of AvailaCr® (Chromium methionine) for all species (EFSA-Q-2006-066)**

  The Rapporteur of the WG introduced the question. This question refers to an application for authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Chromium-methionine (AvailaCr®) as a nutritional additive (functional group: compounds of trace elements) for all species.

  The WG was seeking the Panel's advice on the way to proceed with the development of this opinion taking into consideration the issues that need to be addressed, at a general level related to chromium III and those linked to the product AvailaCr®. Following the advice of the Panel, the applicant will be contacted by EFSA in order to be informed on the current situation.

6. PROGRESS REPORT ON ONGOING WORK

Not discussed

7. NEW REQUESTS TO EFSA RECEIVED FROM THE EUROPEAN COMMISSION

7.1. New applications under Regulation (EC) No 1831/2003

The Commission has forwarded to EFSA four new applications of feed additives seeking authorisation under Regulation (EC) No 1831/2003 since the last plenary meeting. These applications are currently being checked for completeness:

- **Ronozyme® P (6-phytase).** Zootechnical additive for poultry, pigs and sows. GMO product (EFSA-Q-2007-132)

[10] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej547_kokcisan_cff_en,3.pdf
[11] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej549_toyocerin_tk_en,2.pdf

- **MycoCell (*Saccharomyces cerevisiae*).** Zootechnical additive for dairy cows (EFSA-Q-2007-165)
- **Ronozyme® NP (6-phytase).** Zootechnical additive for chickens for fattening. (EFSA-Q-2007-133)
- **BioPlus® 2B (*B. licheniformis, B. subtilis*).** Zootechnical additive for rabbits for fattening (EFSA-Q-2007-166)
- **Levucell SC (*Saccharomyces cerevisiae*).** Zootechnical additive for lambs (EFSA-Q-2007-139).
- **Elancoban® (Monensin sodium).** Coccidiostat for chickens for fattening, turkeys and chickens raised for laying (EFSA-Q-2007-140)

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

Applications considered valid for the start of the assessment:

- **Mn chelate of hydroxy analogue of methionine (Mintrex® Mn).** Nutritional additive for all species (EFSA-Q-2007-094)

  The application and the particulars related to the question on Mintrex® Mn have been considered valid by EFSA on the 3rd September 2007.

  The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

- **Cu chelate of hydroxy analogue of methionine (Mintrex® Cu).** Nutritional additive for all species (EFSA-Q-2007-097)

  The application and the particulars related to the question on Mintrex® Cu have been considered valid by EFSA on the 3rd September 2007.

  The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

- **Zn chelate of hydroxy analogue of methionine (Mintrex® Zn).** Nutritional additive for all species (EFSA-Q-2007-098)

  The application and the particulars related to the question on Mintrex® Zn have been considered valid by EFSA on the 3rd September 2007.

  The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

- **Biosaf Sc 47 (*Saccharomyces cerevisiae*).** Zootechnical additive for all pigs for fattening (EFSA-Q-2007-104)

  The application and the particulars related to the question on Biosaf Sc 47 have been considered valid by EFSA on the 10th August 2007.

  The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

- **Danisco Xylanase (endo-1,4-beta-xylanase).** Zootechnical additive for all turkeys for fattening (EFSA-Q-2007-109)

  The application and the particulars related to the question on Danisco Xylanase have been considered valid by EFSA on the 9th August 2007.

The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

- **Avizyme 1505 (endo-1,4-beta-xylanase, subtilisin, alpha-amylase).** Zootechnical additive for turkeys for fattening **(EFSA-Q-2007-112)**

  The application and the particulars related to the question on Avizyme 1505 have been considered valid by EFSA on the 3rd September 2007.

  The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

8. GENERAL INFORMATION FROM EFSA

Not discussed

9. MISCELLANEOUS

- The agenda for the "EFSA Conference with the Stakeholders: Risk assessment of feed additives in the EU: Present and future" that will take place in Toulouse on 24-25 October was presented to the Panel members.[12]

[12] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178630798347.htm