MINUTES OF THE 28TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 7-9 MARCH 2006)

(ADOPTED ON 19 APRIL 2006)

PARTICIPANTS

Panel Members:
Arturo Anadón (1st and 2nd day), Georges Bories, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht (2nd and 3rd day), Noël Dierick, Gerhard Flachowsky, Anders Franklin, Jürgen Gropp, Anne-Katrine Lundebye Haldorsen, Ingrid Halle, Alberto Mantovani, Kimmo Peltonen, Guido Rychen (2nd and 3rd day), Pieter Wester (1st and 2nd day)

Apologies
Margarita Arboix Arzo, Paul Brantom, Joop de Knecht (1st day), Guido Rychen (1st day), Pascal Sanders, Amadeu Soares, Arturo Anadón and Pieter Wester (3rd day), Wilhelm Windisch

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

European Commission
Marta Ponghellini (DG Health and Consumer Protection); Christoph von Holst (2nd and 3rd day), Anne Mette Jensen (2nd and 3rd day) (DG Joint Research Centre)

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all the participants to the 28th 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.

3. DECLARATIONS OF INTEREST

Dr. Brufau informed that his Institute has been involved in some experiments related to the product Phytase SP 1002 and Calsporin. Therefore he is withdrawn from the related discussions.

4. ADOPTION OF THE DRAFT MINUTES OF THE 27TH PLENARY MEETING ON 25-26 January 2006

The minutes of the 27th plenary meeting of the Scientific Panel held on 25-26 January 2006 were reviewed and adopted.

5. GENERAL INFORMATION FROM EFSA

- The Scientific Co-ordinator (SC) informed the Panel that Mrs. Catherine Geslain-Lanéelle was appointed by EFSA's Management Board as the new Executive Director on 10th February. Mrs. Geslain-Lanéelle has a hearing at the European Parliament on 23 February.
- The call for expressions of interest for the Scientific Committee and the Scientific Panels of the European Food Safety Authority was closed on 17th February. A short list with the candidates for the new Scientific Panels will be sent to the Advisory Forum and the Management Board. The new Panel members will be appointed end of May and the first Plenary meetings with the new Panels will take place in June.
- A new Plenary meeting of the FEEDAP Panel has been scheduled for 22-23 May.
- The SC informed the Panel on the progress on the discussion on the new draft Regulation from the Commission on the implementing rules and guidelines for the authorisation of feed additives. The Commission has sent to the Member States the EFSA's proposal, which was presented in the last Working Group (WG) on Feed Additives of the Standing Committee of the Food Chain and Animal Health, Section Animal Nutrition. EFSA will send to the Commission the rest of the Specific Guidance documents after their adoption (expected in April 2006). Two meetings were held with representatives of the feed additives industry and the pet food industry regarding this issue.
- A meeting took place with a representative of the United Kingdom's FSA and members of the Working Group on Iodine of EFSA regarding the new question from the Commission on the possible impact on iodine deficiency in dairy cows in the UK as a result of the new limits set by the Commission (5 ppm instead of 10 ppm). No scientific evidence has been produced that supports the claim that the new limits would cause deficiency problems in dairy cows.

6. WORK PROGRAM

6.1. Discussion and possible adoption of the following scientific opinions

- **Safety of *Duddingtonia flagrans* for calves (EFSA-Q-2004-115)**

  The Rapporteur of the WG on Micro-organisms introduced the draft opinion. The Commission requested EFSA to deliver an opinion on the safety of this microbial preparation for the target species, consumer, user and the environment. This product is a nematophagous fungus that entraps nematodes. A brief discussion took place on the classification of this product, which could be considered as a feed additive or as a medicinal compound, since it is a biological substitute to anthelmintics. The product is well tolerated for the target species, and no effects are expected on the gut micro-flora. Only an acute toxicity study in rats was provided. Therefore, the FEEDAP Panel cannot fully assess the safety for the consumer and the user of this product with this limited data set. The opinion was adopted after some minor editorial changes.

- **Safety and efficay of the enzyme preparation Phytase SP 1002 for piglets, pigs for fattening, sows, chickens for fattening, turkeys and laying hens (EFSA-Q-2005-030)**

  The Rapporteur of the WG on Enzymes introduced the modified draft opinion. EFSA is requested to deliver an opinion on the efficacy and the safety of Phytase SP 1002 (3-phytase) for the target animals, consumer, user and environment. This product is produced by a genetically modified micro-organism. The GMO Panel assessed the safety aspects of the genetic modification and adopted the corresponding part of the opinion on 28 February 2006. The document was reviewed in detail. The product has demonstrated its efficacy and safety for all target species/categories. It was noted that the tests to determine user safety were not performed with the final product but with a concentrated formulation of the active substance. After some editorial modifications, the opinion was adopted.

- **Safety and efficacy of the enzyme preparation Phyzyme XP for chickens for fattening (EFSA-Q-2005-063)**

  A member of the WG on Enzymes introduced the draft opinion. EFSA is requested to deliver an opinion on the efficacy and the safety of Phyzyme XP (6-phytase) for the target animals, consumer, user and environment. The discussion focussed mainly in the efficacy studies. The evidence provided does not allow to identify a minimum effective dose. The tolerance study was performed with a lower dose than recommended in the currently applicable guidelines. The Panel agreed on to asking further clarifications from the Applicant.

- **Safety and efficacy of Biomin IMB 52 (*Enterococcus faecium*) for chickens for fattening (EFSA-Q-2005-020)**

  The Rapporteur of the WG on Micro-organisms introduced 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 an authorisation for the product Biomin IMB 52 to be used as a feed additive for chickens for fattening (category: zootechnical additives; functional group: gut flora stabilisers). The draft was reviewed in detail. The data provided by the Applicant provides enough evidence to support the efficacy and safety of the product for the target species. The opinion was adopted after some minor changes.

- **Safety and efficacy of Sel-Plex®2000 (EFSA-Q-2005-071)**

  A member of the WG introduced the new draft opinion. The Commission requested EFSA to issue an opinion on the safety and efficacy of the product Sel-Plex®2000, produced by *Saccharomyces cerevisiae* CNCM I-3060.

  The document was reviewed in detail. The discussion focussed on the efficacy and consumer exposure sections where major changes were introduced. For this reason the document will be revised again by the working group in order to be presented in the next plenary meeting in April, for possible adoption.

- **Safety and efficacy of Calsporin (*Bacillus subtilis*) for chickens for fattening (EFSA-Q-2005-150)**

  The Rapporteur of the WG on Micro-organisms introduced 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 an authorisation of the product Calsporin as a feed additive for chickens for fattening (category: zootechnical additives; functional group: gut flora

stabilisers). Efficacy has been demonstrated in three of the four growth trials and a meta-analysis has been conducted with the data of all the studies, which clearly supports the positive effect of the product. The product is well tolerated by the target animals, and no risks for the consumer, user or the environment are foreseen. After some minor editorial changes the opinion was adopted.

- **Safety and efficacy of the product "Amaferm" for dairy cows and cattle for fattening (EFSA-Q-2004-175)**

  The Rapporteur of the Working Group (WG) introduced the modified draft opinion. This question refers to a feed additive application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking an authorisation to use Amaferm, a fermentation product from *Aspergillus oryzae*, as a zootechnical additive (functional group: other zootechnical additives) for dairy cows and beef cattle. The applicant provided new data on a request of the FEEDAP Panel. Efficacy has been confirmed only for dairy cows. Safety for both target animals, user, consumer and the environment has been demonstrated. The opinion was adopted with some editorial modifications.

- **Safety and efficacy of Bio-Feed Pro (proteinase) for chickens for fattening and pigs for fattening (EFSA-Q-2005-090)**

  The Rapporteur of the WG on Enzymes introduced the draft opinion. EFSA has been requested to deliver an opinion on the efficacy and the safety for the target animals, the consumer, the user and the environment of the product "BioFeed Pro", a preparation of proteinase produced by *Bacillus licheniformis*, as a feed additive for chickens for fattening and pigs for fattening. The document was briefly discussed, mainly the efficacy section. However, due to lack of time, it was agreed to discuss it in detail in the next plenary meeting.

- **Guidelines for the assessment of Safety and efficacy of silage additives (EFSA-Q-2004-088)**

  Held back to be discussed with the "Specific guidance for technological additives: silage additives".

6.2. Progress report on ongoing work

Not discussed due to lack of time

7. NEW REQUESTS TO EFSA RECEIVED FROM THE EUROPEAN COMMISSION

7.1. Questions under Directive 70/524/EEC

- **Avizyme 1500 for turkeys for fattening (EFSA-Q-2006-023).**

  An opinion for this product was adopted by the FEEDAP Panel on 20th July 2005. In this opinion it could not be concluded on the safety for the target animals due to a short experimental period. The applicant has now submitted a supplementary dossier to complete the missing data and the Commission has requested EFSA to issue an opinion on the safety of this product for the target species.

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

Applications considered valid for the start of the assessment:

- **L-Lysine (VitaLis Liquid and Dry). Nutritional additive for All Animal Species (EFSA-Q-2005-030).**
  The application and the particulars related to the question on L-Lysine have been considered complete by EFSA on the 6th February 2006.
  The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003. The WG on Aminoacids is dealing with this submission.

- **Bio-Plus 2B (*Bacillus licheniformis* DSM 5749 and Bacillus subtilis DSM 5750). "Other" additive for turkeys for fattening (EFSA-Q-2005-275).**
  The application and the particulars related to the question on Bio-Plus 2B have been considered complete by EFSA on the 14th February 2006.
  The safety and efficacy of the product for use in feedingstuffs containing the coccidiostat E 770, maduramicin ammonium alpha (Cygro 1%) will need to be addressed as foreseen in Regulation (EC) No 1831/2003. The WG on Micro-organisms is dealing with this submission

- **Biosaf Sc 47 (*Saccharomyces cerevisiae* NCYC Sc47). Zootechnical additive for Dairy small ruminants (EFSA-Q-2006-003).**
  The application and the particulars related to the question on Biosaf Sc 47 have been considered complete by EFSA on the 24th February 2006.
  The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003. The WG on Micro-organisms is dealing with this submission.

- **Hemicell (ß-D-Mannanase EC 3.2.1.78). Zootechnical additive for Chickens for fattening (EFSA-Q-2006-004).**
  The application and the particulars related to the question on Hemicell have been considered complete by EFSA on the 20th February 2006.
  The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003. The WG on Enzymes is dealing with this submission.

8. MISCELLANEOUS

- The Opinions on BioSaf SC 47 for lambs (EFSA-Q-2005-149) and Formi™ LHS for piglets and pigs for fattening (EFSA-Q-2004-173) were adopted by written procedure on 9 and 14 February, respectively.
- The SC of the Scientific Committee made a brief presentation on the "Draft opinion of the Scientific Committee on uncertainties in dietary exposure assessment". Comments from all Panels are welcomed by March 10.