MINUTES OF THE 37TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 23-24 JANUARY 2007)

(ADOPTED ON 7 MARCH 2007)

PARTICIPANTS

Panel Members:
Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Pier Sandro Cocconcelli, Bogdan Debski, Noël Dierick, Jürgen Gropp, Ingrid Halle, Christer Hogstrand, Joop de Knecht, Lubomir Leng, Anne Katrine Lundebye-Haldorsen, Alberto Mantovani, Miklós Mézes, Walter Rambeck, Guido Rychen, Atte von Wright, Pieter Wester.

Apologies
Andrew Chesson, Anders Franklin, Carlo Stefano Nebbia.

EFSA
Claudia Roncancio-Peña, Jaume Galobart, Lucilla Gregoretti (scientific staff), Virginia Spurio-Salvi, Kriztina Nagy (administrative staff).

European Commission
Marta Ponghellini, Taina Säteri (1st day) (DG Health and Consumer Protection), Christoph von Holst (DG Joint Research Centre).

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Vice-chair opened the meeting and welcomed the participants to the 37th 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

No interests were declared relevant to the items of the agenda. Joaquim Brufau informed that his institute participated in one trial for Biosaf Sc 47 for calves for rearing. No other interests were declared relevant to the items of the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 36TH PLENARY MEETING ON 5-6 DECEMBER 2006

The minutes of the 36th plenary meeting of the Scientific Panel held on 5-6 December 2006 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of Bonvital (*Enterococcus faecium*) for piglets and pigs for fattening (EFSA-Q-2006-061)**

  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 Bonvital (*Enterococcus faecium*) to be used as a feed additive for piglets and pigs for fattening (category: zootechnical additives; functional group: gut flora stabilisers). This product is provisionally authorised for use in piglets and pigs for fattening, sows and chickens for fattening. The safety of this product for the target species, the consumer, user and the environment has been previously assessed by SCAN with a favourable outcome. Therefore, the current assessment focuses only on the efficacy of this product for piglets and pigs for fattening.

  The studies provided by the applicant support the efficacy of Bonvital for piglets and pigs for fattening. However, the data provided do not support the lowest doses proposed by the applicant.

  The opinion was adopted.[2]

- **Proposal on guidelines/guidance on Environmental risk assessment**

  The Rapporteur of the WG introduced the draft document. EFSA was consulted by the European Commission on the development of guidelines for the assessment of additives for use in animal nutrition, within the framework of Article 7 of Regulation (EC) No 1831/2003. In May 2006, EFSA delivered its proposal on "Guidelines/guidance" to the European Commission, including a draft section on the safety of the additive for the environment.

  In parallel and as a result of a self-tasking activity during 2006, the FEEDAP Panel has been developing an opinion on the Environmental Risk Assessment for the terrestrial and the aquatic compartments. The final outcome of this activity contributed to the preparation of the new section on the safety of the additive for the environment, which will replace the previous one.

  The document was agreed by the Panel, and will be immediately submitted to the European Commission.

- **Proposal on guidelines/guidance on Flavouring Compounds**

  The Rapporteur of the WG introduced the draft document. EFSA was consulted by the European Commission on the development of guidelines for the assessment of additives for use in animal nutrition, within the framework of Article 7 of Regulation (EC) No 1831/2003. In May 2006, EFSA delivered its proposal on "Guidelines/guidance" to the

[1] http://www.efsa.europa.eu/en/science/feedap/feedap_meetings/feedap_36th_plenmeet.html
[2] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej440_bonvital.html

European Commission, but in that proposal, specific guidance for the assessment of flavouring compounds was not included.

A series of modifications were done in the "Common guidance" in order to include the particularities of flavouring compounds. Moreover, the "Specific guidance" for sensory additives was completed with the requirements for flavouring compounds.

The document was agreed by the Panel, and will be immediately submitted to the European Commission.

- **Safety of Bio-Feed® Pro (proteinase) for the consumer (EFSA-Q-2006-181)**

  The Rapporteur of the WG on Enzymes introduced the question and draft opinion. EFSA delivered an opinion on the efficacy and safety of this preparation when used as a feed additive for chickens for fattening, piglets and pigs for fattening (adopted 20 April 2006).[3] In this opinion, the FEEDAP Panel expressed serious concerns on the safety for the consumer. The applicant has provided new data which has been evaluated by the Panel.

  The Panel has proposed some modifications and once they will be done, the document will be sent for written adoption.[4]

- **Safety and efficacy of Toyocerin® (*Bacillus cereus*) for sows (EFSA-Q-2006-037)**

  Not discussed due to lack of time.

- **Safety and efficacy of Biosaf Sc 47 (*Saccharomyces cerevisiae*) for calves for rearing (EFSA-Q-2006-067)**

  Not discussed due to lack of time.

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 three 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:

- **Lantharenol® (**Lanhanum carbonate octahydrate**).** Zootechnical additive for cats **(EFSA-Q-2006-317).**
- **Carophyll® Stay-Pink** (Astaxanthin dimethyldisuccinate). Sensory additive for salmon and trout **(EFSA-Q-2007-018).**
- **Avizyme 1505** (Endo-1,4-beta-xylanase, subtilisin and alpha-amylase). Zootechnical additive for chickens for fattening and ducks **(EFSA-Q-2007-020).**

[3] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/1469.html

[4] The opinion was adopted on 7th February, 2007. http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej451_biofeedpro_consumer.html

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

Applications considered valid for the start of the assessment:

- **Danisco Xylanase (endo 1,4 ß-xylanase).** Zootechnical additive for chickens for fattening, laying hens and ducks for fattening **(EFSA-Q-2006-137)**

  The application and the particulars related to the question on Danisco Xylanase have been considered valid by EFSA on the 21st December 2006.

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

- **MRL on Clinacox 0.5% (diclazuril).** Coccidiostat for chickens for fattening, turkeys for fattening and chickens reared for laying **(EFSA-Q-2006-139)**

  The application and the particulars related to the question on MRL on Clinacox 0.5% have been considered valid by EFSA on the 21st December 2006.

7.3. New questions under Regulation (EC) No 178/2002

- **Zeolite A (sodium aluminium silicate) for the reduction of risk of milk fever in dairy cows (EFSA-Q-2006-184)**

  The FEEDAP Panel issued an opinion on the use of Zeolite for the reduction of milk fever in dairy cows on 8 December 2004.[5] In that opinion, the Panel could not reach a conclusion on safety for the target animals and humans due to the lack of data. New data has now been submitted by the Member State Rapporteur, and the European Commission asked EFSA to issue a new opinion considering the supplementary information provided.

  The deadline proposed by the European Commission is May 2007.

- **Use of feedingstuffs with a high level of calcium for the reduction of risk of milk fever in dairy cows (EFSA-Q-2007-017)**

  The European Commission has asked EFSA to deliver an opinion on the safety for animal health, human health and for the environment of the use of feedingstuffs with a high level of calcium around calving for the reduction of risk of milk fever in dairy cows.

  The deadline proposed by the European Commission is June 2007.

8. GENERAL INFORMATION FROM EFSA

- The Scientific Coordinator (SC) informed the Panel that EFSA's Scientific Committee submitted for public consultation the draft opinion on the "Qualified presumption of safety (QPS) approach for the safety assessment of micro-organisms deliberately added to food and feed". The consultation will be open until 5 March 2007.
- The SC also informed the Panel on the opinion adopted by the Scientific Committee on "Uncertainties in dietary exposure assessment".[6]

[5] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/745.html
[6] http://www.efsa.europa.eu/en/science/sc_commitee/sc_opinions/uncertainty_exp.html

- The Secretariat informed the Panel on the technical hearings held during the last two months.
- A WG of the Standing Committee on Animal Health and Food Chain took place on 19th December to discuss the new guidelines for the assessment of feed additives. Some members of the Panel attended to this meeting and reported back to the Panel.

9. MISCELLANEOUS

- The FEEDAP Panel raised again the issue of indemnities and reimbursement of expenses, and welcomed the actions already taken by EFSA relating to the improvement in the reimbursement of the expenses.