MINUTES OF THE 35TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 21-22 NOVEMBER 2006)

(ADOPTED ON 5 DECEMBER 2006)

PARTICIPANTS

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

Apologies
Joop de Knecht (2nd day), Carlo Stefano Nebbia (2nd day), Guido Rychen (1st day)

EFSA
Claudia Roncancio-Peña, Jaume Galobart, Maria Vittoria Vettori (scientific staff), Ketty Antonelli, Kristina Nagy (administrative staff)

European Commission
Täina Sateri (video conference), Marta Ponghellini (DG Health and Consumer Protection); Christoph von Holst (1st day) (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 35th 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

Joaquim Brufau informed that his institute had participated in some of the studies for the product Hemicell® Feed Enzyme. He withdrew from the discussion on this dossier. Paul Brantom declared his involvement in providing advice on some new products to the company ELANCO and on some general issues. Although he has not provided advice on the specific submission regarding monensin sodium he withdrew from participation in the discussion on this product. No other interests were declared relevant to the items of the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 34TH PLENARY MEETING ON 17-19 OCTOBER 2006

The minutes of the 34th plenary meeting of the Scientific Panel held on 17-19 October 2006 were reviewed and adopted.

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of Hemicell® Feed Enzyme (β-D-mannanase) for chickens for fattening (EFSA-Q-2006-004)**

  The Rapporteur of the WG on Enzymes 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 authorisation of the product Hemicell® Feed Enzyme to be used as a feed additive for chickens for fattening (category: zootechnical additives; functional group: digestibility enhancers).

  The draft was reviewed in detail. The applicant has provided evidence of efficacy for the target species. Safety for the target species has been demonstrated at the recommended dose. No major concerns on the safety for the consumer, user or environment were identified.

  The opinion was adopted subject to some editorial modifications.

- **Maximum Residue Limits for monensin sodium for chickens for fattening and turkeys for fattening (EFSA-Q-2006-167)**

  The Rapporteur of the WG on introduced the draft opinion. EFSA has been requested by the European Commission to take the necessary steps to suggest a single MRL for the coccidiostats Elancoban® and Coxidin® (monensin sodium).

  The FEEDAP Panel proposed provisional MRLs considering the authorised withdrawal time of three days, the most sensitive analytical methods (limit of quantification 0.0025 mg kg^{-1}) and the residue data available for chickens for fattening. For liver, kidney and muscle tissue, a provisional MRL of 0.008 mg kg^{-1} tissue is proposed and for skin/fat 0.025 mg kg^{-1} tissue.

  Due to the similarity in metabolism of monensin in chickens for fattening and turkeys for fattening, the same MRLs as those proposed for chickens can be applied for turkeys. However, the scarcity of turkey data prevents a separate MRL calculation.

  The opinion was adopted subject to some editorial modifications.

- **Safety and efficacy of Selenium enriched yeast (*Saccharomyces cerevisiae*) for all species (EFSA-Q-2005-117)**

  The Rapporteur of the 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 authorisation of the product Selenium enriched yeast (*Saccharomyces cerevisiae*) to be used as a feed additive for all species (category: nutritional additives; functional group: compounds of trace elements).

  The changes introduced in the introduction and efficacy part were reviewed. The discussion focused on safety for the target animals and the tissue deposition section. The document will be modified accordingly and presented in the next plenary meeting in December for possible adoption.

- **Environmental risk assessment: Aquatic compartment (EFSA-Q-2006-079)**

  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 two 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:

- **Biomin C5 (***Pediococcus acidilactici, Enterococcus faecium, Bifidobacterium animalis, Lactobacillus reuteri, Lactobacillus salivarius***).** Zootechnical additive for chickens for fattening **(EFSA-Q-2006-169)**
- **Panaferd-AX** (*Astaxanthin from Paracoccus carotinifaciens*). Sensory additive for salmon and trout **(EFSA-Q-2006-173).**

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

Applications considered valid for the start of the assessment:

- **L-Arginine. Nutritional additive for all species (EFSA-Q-2006-031)**

  The application and the particulars related to the question on L-Arginine have been considered valid by EFSA on the 31st October 2006.

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

- **Availa®Cr (Chromium methionine). Nutritional additive for all species (EFSA-Q-2006-066)**

  The application and the particulars related to the question on Availa®Cr have been considered valid by EFSA on the 25th October 2006.

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

7.3. New questions under Directive 70/524/EEC

- **Bio-Feed Pro (proteinase) (EFSA-Q-2006-181)**

  An opinion on this product was adopted by the FEEDAP Panel on 20 April 2006. EFSA has been requested to assess the safety for the consumer of the enzymatic preparation Bio-Feed Pro (proteinase) based on the new data submitted by the applicant. The deadline proposed by the European Commission is April 2007.

8. GENERAL INFORMATION FROM EFSA

- A member of the Panel reported on the meeting of the WG of the Standing Committee on Animal Health and Food Chain dealing with the new guidelines for the assessment of feed additives, which took place on 6th November.

- The Scientific Committee of EFSA is setting a WG on Transparency. One Panel member volunteered to attend this WG in representation of the whole Panel.
- The public consultation on Environmental Risk assessment was closed on 31 October 2006. Several comments have been received from different institutions, industry and Member States. The comments received will be revised by the WG in order to contribute to finalise the opinion.

9. MISCELLANEOUS

None