MINUTES OF THE 32ND PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 11-12 JULY 2006)

(ADOPTED ON 12 SEPTEMBER 2006)

PARTICIPANTS

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

Apologies
Anne-Katrine Lundebye Haldorsen, Guido Rychen (1st day)

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

European Commission
Giuseppe Simone (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 32nd 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.

4. ADOPTION OF THE DRAFT MINUTES OF THE 31ST PLENARY MEETING ON 14-15 JUNE 2006

The minutes of the 31st plenary meeting of the Scientific Panel held on 14-15 June 2006 were reviewed and adopted.

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of Kokcisan 120G for chickens for fattening (EFSA-Q-2006-006)**

  The Commission had requested EFSA to conduct a safety assessment of this product, based on the new data provided by the applicant in the supplementary dossier.

  A first opinion on Kokcisan 120G adopted in 2004 identified that the data provided by the applicant was insufficient for any conclusions to be reached on efficacy and consumer safety. For this reason the applicant has conducted further studies to address the inadequacies previously identified, and the studies submitted have been reviewed in this opinion.

  The Rapporteur of the working group (WG) introduced the draft opinion, which was reviewed in detail. The FEEDAP Panel could not derive an ADI or MRL from the submitted data since no adequate chronic study was available for this product. Regarding the environmental risk assessment, it cannot be excluded that the use of Kokcisan 120G at the recommended dose range poses a risk for the terrestrial and aquatic compartments.

  Kokcisan 120G has been shown to be efficacious against *Eimeria* infection, according to the new study submitted by the applicant. The opinion was adopted after some editorial modifications.

- **Safety of Coxidin® (monensin sodium) for chickens for fattening and turkeys for fattening (EFSA-Q-2006-005)**

  The Commission had requested EFSA to conduct a safety assessment of Coxidin® for chickens and turkeys for fattening, based on the new data provided by the applicant in the supplementary dossier

  A first opinion on Coxidin® adopted in 2005 identified that the data provided by the applicant was insufficient for any conclusions to be reached on the metabolism and residues of monensin sodium. For this reason the applicant has conducted further studies to address the inadequacies previously identified and the studies submitted have been reviewed on this opinion.

  The Rapporteur of the WG introduced the draft opinion, which was reviewed in detail. The FEEDAP Panel considers skin/fat as the target tissue and monensin-sodium as the marker residue. A MRL of 0.05 mg kg^{-1} has been proposed for skin/fat. The limit of quantification (0.006 mg kg^{-1}) can be used as substitute for the MRL for liver, kidney and muscle. The opinion was adopted after some editorial modifications.

- **Safety of Biacton (*Lactobacillus farciminis*) for chickens for fattening, turkeys and laying hens (EFSA-Q-2004-177)**

  The Rapporteur of the WG on Micro-organisms introduced the draft opinion. EFSA is requested to deliver an opinion on the safety of this microbial preparation for the target species chickens for fattening, turkeys and laying hens.

  The draft opinion was reviewed. The applicant has provided enough evidence, in the form of three tolerance studies to conclude that the additive is safe for chickens for fattening, turkeys and laying hens.

  The opinion was adopted with minor editorial modifications.

- **Safety and efficacy of Biosaf Sc 47 (*Saccharomyces cerevisiae*) for dairy small ruminants (EFSA-Q-2006-003)**

  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 authorisation of the product Biosaf Sc 47 to be used as a feed additive for dairy small ruminants (category: zootechnical additives; functional group: other zootechnical additives).

  The draft was reviewed in detail. Due to the fact that the mode of action of yeasts in the rumen is essentially similar in cattle than in goats and sheep, the FEEDAP Panel considered that the two studies provided by the applicant are sufficient to demonstrate efficacy. The additive is also considered safe for the target species.

  The opinion was adopted with minor editorial modifications.

- **Safety and efficacy of BioPlus 2B (*Bacillus subtilis* and *B. licheniformis*) for turkeys (EFSA-Q-2005-075)**

  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 authorisation to modify the Annex entry of Directive 70/524/EEC to allow the use of the product BioPlus 2B in turkey feed containing the coccidiostat maduramicin ammonium.

  The draft was reviewed in detail. The FEEDAP Panel delivered an opinion on this product on 12th November 2003, which concluded that an *in vivo* study would be necessary to conclude on the compatibility of both products. The *in vivo* trial has been now submitted by the applicant and showed that the coccidiostat did not influence the efficacy of BioPlus 2B or the amount of caecal viable spores. BioPlus 2B can therefore be considered as compatible with the coccidiostat maduramicin ammonium.

  The opinion was adopted.

- **Safety and efficacy of Biosaf Sc 47 (*Saccharomyces cerevisiae*) for horses (EFSA-Q-2005-025)**

  Not discussed due to the lack of time.

5.2. Discussion of the following scientific opinions

- **Carotenoids: Part II. Capsanthin, citranaxanthin and cryptoxanthin. (EFSA-Q-2003-060)**

  The Commission had requested EFSA to conduct a safety assessment on the use of capsanthin (E160c), beta-apo-8'-carotenal (E160e), ethyl ester of beta-apo-8'carotenic acid (E160f), lutein (E161b), cryptoxanthin (E161c), zeaxanthin (E161h), citranaxanthin (E161i), astaxanthin (E161j) in feedingstuffs for laying hens, other poultry, salmon, trout, on the basis of currently available scientific literature. The FEEDAP Panel has prepared a series of documents dealing with the assessment of these carotenoids.

  The opinion entitled "Part I. General Principles and Asthaxanthin" was adopted on the 30th November, 2005. The document presented for discussion during this plenary, has been presented by the Rapporteur of the working group and deals with the remaining three red-carotenoids: capsanthin, citranaxanthin and cryptoxanthin.

The draft was reviewed in detail and some modifications have been proposed by the Panel. However due to the lack of time the whole opinion could not be discussed and revised. The document will be tabled again in the next plenary meeting, giving high priority.

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:

- **VevoVitall® (Benzoic acid). Zootechnical additive for pigs for fattening (EFSA-Q-2006-056).**
- **Ronozyme P/Bio Feed Phytase (6-Phytase produced by *Aspergillus oryzae* DSM 14223). Zootechnical additive for ducks (EFSA-Q-2006-060).**
- **Bonvital (*Enterococcus faecium* DSM 7134). Zootechnical additive for pigs for fattening, piglets and dogs (EFSA-Q-2006-061).**
- **Sorbiflore (*Lactobacillus rhamnosus* MA27/6B and *Lactobacillus farciminis* MA27/6R). Zootechnical additive for piglets (EFSA-Q-2006-062).**

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

Applications considered valid for the start of the assessment:

- **Quantum™ Phytase 5000L/2500D (6-Phytase). Zootechnical additive for chickens for fattening, laying hens, ducks for fattening, turkeys for fattening and piglets (EFSA-Q-2006-025).**

  The application and the particulars related to the question on Quantum™ Phytase 5000L/2500D have been considered complete by EFSA on the 23rd June 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.

- **ColiCure (*Escherichia coli* LMG S-17146). Zootechnical Additive for horses (EFSA-Q-2005-167)**

  The application and the particulars related to the question on ColiCure have been considered complete by EFSA on the 21st June 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.

8. MISCELLANEOUS

- The Deputy Executive Director and Director of Science, Dr. Herman B.W.M. Koëter was invited to the plenary meeting in order to provide further clarifications regarding the

allowances established for the experts, as this issue was already raised by the Panel in the Plenary meeting held in June 2006.

Dr. Koëter informed the Panel on the outcome of the discussions held at the Management Board (MB) level and encouraged the Panel to express their views/concerns in a written form to be transmitted directly to the MB. Another proposal made was the possibility that a member(s) of the Panel(s) could be invited to attend a meeting of the MB to bring this issue forward.

- Due to the establishment of the new FEEDAP Panel in June 2006, the composition of the different standing and ad-hoc working groups were modified allowing the new Panel experts to join them. Furthermore, new working groups have been established and/or existing working groups were converted into standing working groups in order to cover the needs of the Panel.
- The FEEDAP Panel will launch a public consultation aimed at establishing a harmonised scientific approach in Europe to assess the environmental risks posed by additives, products and substances used in animal feed, including fish feed. The consultation period will be open until 31st October 2006 and the document is available at the EFSA's website (http://www.efsa.europa.eu/en/science/feedap/feedap_consultations.html).