MINUTES OF THE 33RD PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 12-13 SEPTEMBER 2006)

(ADOPTED ON 17 OCTOBER 2006)

PARTICIPANTS

Panel Members:
Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Noël Dierick, Anders Franklin, Jürgen Gropp, Christer Hogstrand, Lubomir Leng, Alberto Mantovani, Miklos Mézes, Carlo Stefano Nebbia (1st day), Walter Rambeck, Guido Rychen, Atte von Wright, Pieter Wester

Apologies
Ingrid Halle, Joop de Knecht, Carlo Stefano Nebbia (2nd day)

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

European Commission
Täina Sateri (video conference), Marta Ponghellini (DG Health and Consumer Protection); 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 33rd 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 has participated in some of the studies for the product Safizym X. No other interests were declared relevant to the items of the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 32ND PLENARY MEETING ON 11-12 JULY 2006

The minutes of the 32nd plenary meeting of the Scientific Panel held on 11-12 July 2006 were reviewed and adopted.

5. WORK PROGRAM

5.1. Discussion and possible adoption 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 and other poultry, salmon and trout. The FEEDAP Panel has prepared a series of documents dealing with the assessment of these carotenoids, the first one was adopted on the 30th November, 2005 and is entitled: "Part I. General Principles and Asthaxanthin".

  The draft document dealing with the remaining three red-carotenoids: capsanthin, citranaxanthin and cryptoxanthin was reviewed in detail. No safety concerns were raised by any of the three additives.

  Regarding Capsanthin, the FEEDAP Panel considers that capsanthin/capsorubin derived from poultry fed paprika oleoresins at concentrations adequate for egg and skin colour will make only a negligible contribution to the total human exposure. For citranaxanthin, the Panel does not see an urgent call for action; however, a full re-evaluation of the compound in the near future would be appropriate. Considering the absence of commercially available beta-cryptoxanthin for poultry diets and its questionable, if any, efficacy in pigmenting poultry eggs and tissues (due to its low intestinal absorption), the FEEDAP Panel sees no reason at present to maintain the approval of beta-cryptoxanthin as a sensory additive.

  The opinion was adopted with minor editorial modifications.

- **Safety and efficacy of Elancoban® (monensin sodium) for calves for rearing and cattle for fattening (EFSA-Q-2005-168)**

  The Rapporteur of the WG on Coccidiostats 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 Elancoban® (monensin sodium) to be used as a feed additive for calves for rearing and cattle for fattening (category: coccidiostats).

  The draft was reviewed in detail and the Panel considered that Elancoban® is effective in the dose range 30-45 mg Mo-Na kg^{-1} complete feedingstuffs. However, the absence of complete feed intake data in some of the trials does not allow an exact conversion of mg kg^{-1} body weight data into mg kg^{-1} complete feed, but only an approximation. Since consumer exposure will not exceed the ADI under the worst case conditions, the FEEDAP Panel does not see the necessity for establishing MRLs and consequently setting a withdrawal period.

  The opinion was adopted with minor editorial modifications.

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

  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 horses (category: zootechnical additives; functional group: other zootechnical additives).

The draft was reviewed in detail. The applicant has provided enough evidence to support the efficacy and the safety of this additive for the target species.

The opinion was adopted with minor editorial modifications.

- **Safety and efficacy of Levucell SC20/SC10ME (*Saccharomyces cerevisiae*) for leisure horses (EFSA-Q-2005-234)**

  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 Levucell SC20/SC10ME to be used as a feed additive for leisure horses (category: zootechnical additives; functional group: other zootechnical additives).

  The draft was reviewed in detail. The evidence provided by the applicant (one efficacy study) is not considered adequate to demonstrate the efficacy of this product. The tolerance study shows that the additive is well tolerated by the target species.

  The opinion was adopted with some editorial modifications.

- **Safety and efficacy of 035 (*Bacillus subtilis*) for chickens for fattening (EFSA-Q-2005-237)**

  Not discussed due to lack of time

- **Safety and efficacy of Safizym X (endo-1,4-beta-xylanase) for piglets (EFSA-Q-2005-276)**

  Not discussed due to lack of time

- **Safety and efficacy of Phyzyme XP 5000L/5000G (6-phytase) for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening, piglets (weaned), pigs for fattening and sows (EFSA-Q-2005-080)**

  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 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:

- **AvailaCr® (Chromium Methionine). Nutritional additive for all species (EFSA-Q-2006-066).**
- **Biosaf Sc 47 (*Saccharomyces cerevisiae* NCYC Sc47). Zootechnical additive for calves for rearing (EFSA-Q-2006-067).**
- **L-Histidine. Nutritional additive for salmonids (EFSA-Q-2006-079).**
- **Natugrain Wheat TS (Endo 1,4 ß-xylanase) for turkeys for fattening (EFSA-Q-2006-119).**

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

Applications considered valid for the start of the assessment:

- **L-Histidine. Nutritional additive for salmonids (EFSA-Q-2006-079)**

  The application and the particulars related to the question on L-Histidine have been considered valid by EFSA on the 7th September 2006.

  The additive has been already evaluated by EFSA in 2005, under Directive 82/471/EEC. The application has been transferred to Regulation (EC) 1831/2003. EFSA shall deliver an opinion on the method of analysis and on the post-market monitoring of this product when used as feed additive for salmonids.

- **VevoVitall (benzoic acid). Zootechnical additive for pigs for fattening (EFSA-Q-2006-056)**

  The application and the particulars related to the question on VevoVitall have been considered valid by EFSA on the 24th August 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 82/471/EEC

- **Application for authorisation of the product "ATIS AF Animal Feed inactivated yeast" (Biomass yeast obtained from cultivation of *Candida utilis* on wood sugars) for all species. (EFSA-Q-2006-120)**

  EFSA has been requested by the European Commission to deliver an opinion on the safety for the target animals, consumer, worker, user and environment of the product "ATIS AF Animal Feed inactivated yeast", which is a yeast biomass of inactivated Torula yeast (*Candida utilis*) cultivated in wood sugars. An ad-hoc WG has been created to deal with this question. The deadline proposed for the European Commission for the adoption of the opinion is February 2007.

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

- **Vitamin A contents of products of animal origin. Vitamin A addition to feedingstuffs as nutritional additive. Question under Reg. 178/2002. (EFSA-Q-2006-121)**

  The Commission has requested EFSA to deliver an opinion on the safety for the animal and the consumer of the use of high levels of vitamin A, according to Article 29 of Regulation (EC) 178/2002. EFSA will address the following points according to the terms of reference proposed by the European Commission: i) revision of two recent reports (UK and France) and/or other available updated scientific information; ii) estimation of the dietary contribution of vitamin A for European consumers from the various different sources and, if required modification of the maximum permitted levels in feed authorised in accordance with Regulation (EC) 1831/2003, and iii) evaluation of the zootechnical implications of lowering the levels of Vitamin A permitted in feed, and the assessment for the safety for the animals and the environment.

  The deadline proposed for the European Commission for the adoption of the opinion is February 2007.

8. MISCELLANEOUS

- The dates for the Plenary Meetings in 2007 were agreed.
- Christoph von Holst, Operating Manager from the Community Reference Laboratory (CRL) made a presentation on the mission and tasks of the CRL with regards to the authorisation of feed additives.