MINUTES OF THE 30TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 22-23 MAY 2006)

(ADOPTED ON 2 JUNE 2006)

PARTICIPANTS

Panel Members:
Arturo Anadón, Georges Bories, Paul Brantom, Andrew Chesson, Pier Sandro Cocconcelli, Noël Dierick, Jürgen Gropp, Joop de Knecht, Gerhard Flachowsky, Anne-Katrine Lundebye Haldorsen (2nd day), Ingrid Halle, Alberto Mantovani, Kimmo Peltonen, Guido Rychen (2nd day), Pieter Wester

Apologies
Margarita Arboix Arzo, Joaquim Brufau de Barberà, Anders Franklin, Anne-Katrine Lundebye Haldorsen (1st day), Guido Rychen (1st day), Pascal Sanders, Amadeu Soares, Wilhelm Windisch

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

European Commission
Marta Ponghellini, Täina Sateri (DG Health and Consumer Protection); Anne Mette Jensen (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 30th Plenary meeting of the FEEDAP Panel. This is the last Plenary meeting of the current 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 29TH PLENARY MEETING ON 19-20 April 2006

The minutes of the 29th plenary meeting of the Scientific Panel held on 19-20 April 2006 were reviewed and adopted.

5. GENERAL INFORMATION FROM EFSA

- The Scientific Co-ordinator (SC) made a brief presentation of the activities and achievements of the FEEDAP Panel from 2003 to 2006, regarding the number of opinions received/adopted, self-task activities, number of working groups held according to the different categories and applications received under the new regulation, The SC acknowledged the Panel for their valuable work and for their commitment and contribution during this period.
- The European Food Safety Authority organised on the 15th May in Brussels a Discussion Forum with National Experts on the scientific assessment of GMOs in the EU. One member of the FEEDAP Panel was invited to participate in this Forum, where discussions were held on EFSA's scientific assessments of the potential risks of GMOs for human health and environmental safety.
- A meeting was held between the FEEDAP Scientific Secretariat and representatives of the Unit D2, DG SANCO, of the European Commission on the development of guidelines/guidance for the assessment of additives for use in animal nutrition. The basis for discussion was the contents of the set of documents prepared by EFSA and further explanations were requested by the European Commission. Additional meetings are foreseen in the future to continue with this discussion.

6. WORK PROGRAM

6.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of Levucell SC20/SC10ME (*Saccharomyces cerevisiae*) for dairy goats and dairy ewes (EFSA-Q-2005-176)**

  The Rapporteur of the working group (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 Levucell SC20/SC10ME to be used as a feed additive for dairy goats and dairy ewes (category: zootechnical additives; functional group: other zootechnical additives). The draft was reviewed in detail. The Panel identified some problems with the data presented to demonstrate efficacy and with the way the application rate was expressed. It has been decided that the draft should be reviewed by the WG before resubmitting it to the Plenary.

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

  The Rapporteur of the WG 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 Elancoban® a coccidiostat containing monensin sodium, to be used as a feed additive for calves for rearing and cattle for fattening.

  The draft was reviewed in detail. The Panel identified some additional problems with the limit of detection of the analytical method to measure monensin sodium in tissues which has consequences for the setting of the MRLs, based on the existing metabolism/residue data. The Panel agreed to ask the applicant for further clarification on the details of the analytical method, or, if necessary, the submission of new information in order to set the MRLs.

- **Environmental risk assessment – Self-task (EFSA-Q-2004-078)**

The Rapporteur of the WG introduced the working document on the terrestrial and aquatic compartments. After extensive discussion during the meeting some proposals for further modifications on the structure of the document have been suggested, in order to improve its clarity.

The Panel agreed that the document should be made available for public consultation via the EFSA's website, after minor revision.

- **Safety and efficacy of Belfeed 1100MP/ML (Endo-1,4-beta xylanase EC 3.2.1.8) for ducks for fattening (EFSA-Q-2005-115)**

  Not discussed due to lack of time.

- **Safety of the enzyme preparation Avizyme 1500 for turkeys for fattening (EFSA-Q-2006-023)**

  Not discussed due to lack of time.

6.2. Discussion of the following scientific opinions

- **Safety and efficacy of Natuphos® (3-phytase). Change of production strain and double concentration (EFSA-Q-2005-116)**

  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 an authorisation of a new production strain (*Aspergillus niger* CBS 101.672) of the product Natuphos® and for the authorisation of new liquid and solid formulations with double concentration.

  Some of the tolerance studies presented in the dossier (for laying hens, turkeys and sows) did not fulfil the requirements set by the SCAN in the guidelines for the assessment of enzymes. The Panel agreed that the evidence presented in the dossier and the supplementary information submitted by the Applicant, does not allow conclusions to be drawn on the safety for laying hen, turkey and sow.

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

  Not discussed due to lack of time.

7. PROGRESS REPORT ON ONGOING WORK

Not discussed.

8. NEW REQUESTS TO EFSA RECEIVED FROM THE EUROPEAN COMMISSION

8.1. New applications under Regulation (EC) No 1831/2003

The Commission has forwarded to EFSA two new applications of a feed additive seeking authorisation under Regulation (EC) No 1831/2003 since the last plenary meeting. These applications are currently being checked for completeness:

- **Toyocerin® (*Bacillus cereus* var *toyoi*). Zootechnical additive for sows (from service to weaning) (EFSA-Q-2006-037).**
- **Oral Iron Dextran 20% (Iron dextran usher-20). Nutritional additive for piglets, mink and fox (EFSA-Q-2006-036)**

8.2. New Questions under Directive 70/524/EEC

- **Kofa®Grain –pH 5- (mixture of sodium benzoate, propionic acid and sodium benzoate) as a preservative for cattle for fattening. (EFSA-Q-2006-032)**

  EFSA is requested to deliver an opinion on the safety and efficacy of this product as a preservative for cattle for fattening.

9. MISCELLANEOUS

- **Question on the use of iodine in feedingstuffs (EFSA-Q-2005-283).**

  Following the Opinion issued by EFSA on the use of iodine in feedingstuffs (adopted on 25 January 2005)[1], the Commission has adopted a Regulation to reduce the levels of iodine in feedingstuffs for laying hens and dairy cows from 10 ppm to 5 ppm.

  EFSA has been requested to issue an opinion on the use of iodine in feedingstuffs for dairy cows, in particular whether the currently authorised levels (5 mg kg^{-1} complete feed) may undermine animal or human health.

  An extensive literature review has been conducted in order to identify new information on the effects of iodine at this level, as well as contacts with UK representatives. It has become evident that no new information is available to support levels of iodine in feedingstuffs for dairy cattle higher than 5 ppm (i.e. 10 ppm). For this reason EFSA does not see any justification to proceed to a revision of the previous opinion. A letter has been sent to the European Commission to inform them on this issue.

The Chairman of the FEEDAP Panel closed the meeting, thanking all the Panel members for their work during this three-year mandate.

[1] EFSA, 2005. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the request from the Commission on the use of iodine in feedingstuffs. (EFSA-Q-2003-058) http://www.efsa.eu.int/science/feedap/feedap_opinions/808_en.html