MINUTES OF THE 26TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 29-30 NOVEMBER 2005)

(ADOPTED ON 25 JANUARY 2006)

PARTICIPANTS

Panel Members:
Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht (1st day), Anders Franklin, Jürgen Gropp, Anne-Katrine Lundebye Haldorsen, Ingrid Halle, Alberto Mantovani, Kimmo Peltonen, Guido Rychen, Pascal Sanders (1st day), Pieter Wester, Wilhelm Windisch

Apologies
Arturo Anadón, Margarita Arboix Arzo, Joop de Knecht (2nd day), Noël Dierick, Gerhard Flachowsky, Pascal Sanders (2nd day), Amadeu Soares

EFSA
Liisa Vahteristo, Jaume Galobart, Gloria López-Gálvez, Claudia Roncancio, Lucilla Gregoretti (scientific staff), Ketty Antonelli (administrative staff)

European Commission
Rosella Brozzi Bettio (DG Health and Consumer Protection)

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all the participants to the 26th 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, after the introduction of an additional point for discussion; an overview of the environmental risk assessment working document, and after deletion of the item for discussion on the product Aquasta for salmon and trout.

3. DECLARATIONS OF INTEREST

Dr. Brufau informed that his institute has been involved in some experiments related to the products Toyocerin, Vevovitall and Phytase SP 1002. Prof. Windisch also informed that he is

currently involved in some experimental work related to the product VevoVitall. These two Panel members therefore withdrew from related discussions.

4. ADOPTION OF THE DRAFT MINUTES OF THE 25TH PLENARY MEETING ON 14 November 2005

The minutes of the 25th plenary meeting of the Scientific Panel held on 14 November 2005 were reviewed and adopted. The minutes of the 24th plenary meeting had been adopted by written procedure and were distributed to all the members.

5. GENERAL INFORMATION FROM EFSA

- The Scientific Co-ordinator (SC) informed the Panel that documents related to the guidelines/guidance for the assessment of additives for use in animal nutrition that were agreed in the last plenary were submitted to the European Commission as the outcome of the consultation. A meeting between members of DG SANCO unit on Animal Nutrition and scientific staff of the FEEDAP team is foreseen necessary in order to discuss future actions.
- The call for expressions of interest in membership of the Scientific Committee and Scientific Panels of the European Food Safety Authority was published on the EFSA website on the 22nd November. The deadline to submit applications is 7 January. The applications can be submitted on-line at http://www.efsa.eu.int/opportunities/general_advice/catindex_en.html.
- Mr. Podger, the former Executive director, left EFSA on 25th November. The Deputy Director and Director of Science, Mr. H. Koëter will be acting as Executive Director until the new Executive Director is appointed.

6. WORK PROGRAM

6.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of the product "Amaferm" for dairy cows and cattle for fattening (EFSA-Q-2004-175)**

  The Rapporteur of the Working Group (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 to use Amaferm, which is a fermentation product from *Aspergillus oryzae*, as a zootechnical additive (functional group: other zootechnical additives) for dairy cows and beef cattle. The discussion focussed mainly on the characterisation of the product and on the studies to demonstrate efficacy. The Panel agreed to ask the applicant for further clarification on the efficacy data for cattle for fattening and also on some details on the safety of the *A. oryzae* strain. According to the provisions of Article 8 of Regulation (EC) 1831/2003 when supplementary information is requested, the Authority will extend the time limit for issuing its opinion, after consultation with the applicant.

- **Safety of the chelated forms of iron, copper, manganese and zinc with synthetic feed grade glycine (EFSA-Q-2004-155)**

  The Rapporteur of the WG introduced the modified draft opinion. EFSA is requested to deliver an opinion on the safety of the chelated forms of iron, copper, manganese and zinc with synthetic feed grade glycine for the target animals, consumer, user and environment. The document was reviewed in detail and some changes were introduced. The Panel considered that the use of food grade glycine in the production of these chelates does not

introduce additional safety concerns that are not covered by the safety assessment of the individual components.

The opinion was adopted after some changes were introduced.

- **Safety and efficacy of Vevovitall® (benzoic acid) for weaned piglets (EFSA-Q-2005-007)**

  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 to use Vevovitall®, which is based on benzoic acid, for weaned piglets under the category of zootechnical additives (functional group: other zootechnical additives).

  The document was reviewed in detail and some changes were introduced on the characterisation and microbiological safety of the product. The Panel considered that the product is efficacious and safe, even though a safety margin for the target species could not be determined.

  The opinion was adopted after some editorial modifications.

- **Safety of use of colouring agents in animal nutrition – red pigmenting carotenoids (astaxanthin) (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 focused in a first step in the red-colouring carotenoids: astaxanthin, capsanthin, citranaxanthin and cryptoxanthin.

  The document presented in the plenary is a first of a series of documents dealing with the assessment of carotenoids and it dealt with the general principles and astaxanthin. The Panel agreed on this approach and the opinion on astaxanthin was adopted.

- **Modification of the terms of authorisation of Toyocerin® (*Bacillus cereus* var. *toyoi*) (EFSA-Q-2005-021)**

  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 to modify the Annex to Directive 70/524/EEC to allow the use of the product Toyocerin®, which is based on *Bacillus cereus* var. *toyoi* in feed for chickens for fattening containing the coccidiostats diclazuril, narasin-nicarbazin and maduramicin ammonium.

  The document was reviewed in detail. The discussion focussed on the studies that the company provided to demonstrate the compatibility *in vivo* between the micro-organism and the coccidiostats. The Panel concluded that on the basis of the data provided, nothing suggests than an incompatibility exists between the additive and the cocccidiostats, either on storage or when fed to chickens for fattening.

  The opinion was adopted after some editorial modifications.

- **Safety of new formulation of the enzyme preparation Grindazym GP and its extension to ducks (EFSA-Q-2005-067 & 068)**

The Rapporteur of the WG on Enzymes introduced the draft opinion. EFSA is requested to deliver an opinion on the safety of the new granulate form of the enzyme preparation of trade name Grindazym GP, enzyme E 1609, which is a preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 600.94), for the consumer, the user, the worker, the environment and for the target animal categories chickens for fattening, turkeys for fattening and piglets, and also to assess the safety of this enzyme preparation for the target species ducks for fattening.

The Panel carefully reviewed the draft opinion and concluded that the additive is safe for the ducks for fattening and it had no safety concerns of the new granulated formulation for the proposed use.

The opinion was adopted after some editorial modifications.

6.2. Discussion a of the following scientific opinions

- **Safety and efficacy of the enzyme preparation Phytase SP 1002 for piglets, pigs for fattening, sows, chickens for fattening, turkeys and laying hens (EFSA-Q-2005-030)**

  EFSA is requested to deliver an opinion on the safety of the enzyme preparation "Phytase SP 1002", which is a preparation of 3-phytase, EC 3.1.3.8, produced by *Hansenula polymorpha* (DSM 15087), for the target animals, the user, the consumer and the environment and the efficacy. This opinion will be co-adopted by the GMO and FEEDAP Panels. The applicant has been requested to provide some information to allow full assessment of the safety of the product to be made.

  A member of the WG on Enzymes presented the draft document which was reviewed by the Panel. The discussion focused on the studies to demonstrate the efficacy of the additive. The Panel asked the WG to introduce some modifications to the document.

- **Self-task on the development of an approach for the environmental risk assessment of additives and products for use in animal nutrition**

  The Rapporteur of the WG presented the general approach taken for the development of this document and invited the panel members to contribute on some specific issues, as well as to provide other general comments. The document will be circulated to all the panel members after some modifications.

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 one new application of a feed additive seeking authorisation under Regulation (EC) No 1831/2003 since the last plenary meeting. This application is currently being checked for completeness:

- **Microbiological product 035 (*Bacillus subtilis* DSM 17299). Zootechnical additive for chickens for fattening (EFSA-Q-2005-237).**

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

Applications considered valid for the start of the assessment:

- **Natuphos® (3-Phytase). Change of producing strain and double concentration (EFSA-Q-2005-116)**

The application and the particulars related to the question on Natuphos® (3-Phytase) have been considered complete by EFSA on the 26th October 2005.

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.

- **Levucell SC20/Levucell SC10ME (*Saccharomyces cerevisiae* CNCM I-1077). Zootechnical Additive for dairy goats and dairy ewes (EFSA-Q-2005-176)**

  The application and the particulars related to the question on Levucell SC20/Levucell SC10ME for dairy goats and dairy ewes have been considered complete by EFSA on the 8th November 2005.

  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

None