# MINUTES OF THE 24TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

## (PARMA, 19-20 OCTOBER 2005)

### (ADOPTED ON 28 NOVEMBER 2005)

## PARTICIPANTS

Panel Members:
Arturo Anadón, Margarita Arboix Arzo, Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Noël Dierick, Gerhard Flachowsky, Anders Franklin, Jürgen Gropp, Anne-Katrine Lundebye Haldorsen, Ingrid Halle, Alberto Mantovani, Kimmo Peltonen, Guido Rychen, Pascal Sanders, Amadeu Soares, Wilhelm Windisch

Apologies
Pieter Wester

EFSA
Liisa Vahteristo, Jaume Galobart (scientific staff), Dominique Byron, Virginia Spurio, Ketty Antonelli (administrative staff)

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

## 1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all the participants to the 24th 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 item for discussion on the product Phytase SP 1002 was removed and the item on coccidiostat Coxidin® was put forward for discussion and possible adoption.

## 3. DECLARATIONS OF INTEREST

No interests were declared to the items of the agenda.

## 4. ADOPTION OF THE DRAFT MINUTES OF THE 23RD PLENARY MEETING ON 21-22 September 2005

The minutes of the 23rd plenary meeting of the Scientific Panel held on 21-22 September 2005 were reviewed and adopted. The previously adopted minutes of the 22nd plenary meeting were distributed to all the members.

## 5. GENERAL INFORMATION FROM EFSA

- The Scientific Co-ordinator (SC) informed the Panel that the process of verification of notifications of feed additives submitted to EFSA under Article 10 of Regulation (EC) No 1831/2003 has almost been completed. The deadline for submitting the verification results to the Commission is 7 November 2005 when the products concerned shall be entered in the Register. The final number of additives, products and substances notified to the European Commission was approximately 11000.
- The panel members were informed that the deadline for the request for the Member States to nominate competent organisations in the fields of EFSA's mission for a scientific network according to Article 36 of Regulation 178/2002 and Commission Regulation 2230/2004 has been extended until 1st December.
- In relation to the Parma meetings the SC invited the experts to reserve their hotel accommodation well in advance in order to avoid any availability problems. The Panel members asked for the possibility to know beforehand the dates of any bigger fairs in order to avoid problems with the booking of accommodation.
- Until now no new information on the call for experts for the scientific committee and panels of EFSA for 2006 is available. The SC promised to keep the Panel informed about the developments and the eventual publication of the call.

## 6. WORK PROGRAM

### 6.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of the product "Formi™LHS" for weaned piglets and pigs for fattening (EFSA-Q-2005-173)**

  The Rapporteur of the WG introduced a modified draft opinion. This question refers to an application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking an authorisation to use this product based on potassium diformate as a feed additive for piglets and pigs for fattening, under the category of zootechnical additives, functional groups: gut flora stabilisers and other zootechnical additives. The discussion focussed mainly in the studies to demonstrate efficacy. The Panel agreed to ask the applicant for further clarification on the efficacy data. 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 chemically synthesized glycine (EFSA-Q-2004-155)**

  Not discussed due to lack of time.

- **Safety and efficacy of the coccidiostat Coxidin® (EFSA-Q-2005-024)**

  This question refers to an application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Coxidin®, a coccidiostat consisting of monensin sodium, to be used as a feed additive for chickens for fattening and turkeys for

fattening. Therefore, EFSA shall deliver an opinion on the safety for the target animals, consumer, user, and the environment, and on the efficacy of this product. Following a response from the applicant the modified draft opinion was introduced to the members by the rapporteur of the Working Group (WG). The Panel reviewed in detail all sections of the opinion and following some proposals for minor changes the opinion was adopted.

### 6.2. Discussion on the draft implementing rules and guidelines/guidance for authorisation of additives for use in animal nutrition

The rapporteur of the WG on Guidelines presented the general structure of the approach and the different documents that will be sent to the European Commission as guidelines. The document comprises the Implementing rules, Annex I containing the application form, Annex II containing the "Guidelines laying down the principles for the establishment of dossiers submitted with applications for the authorisation of additives for use in animal nutrition" and Annex III containing a list of animal categories and their definition.

The documents were reviewed in detail by the Panel, and some modifications were introduced. Some changes were introduced in the implementing rules to take account of the new approach proposed by EFSA.

The Panel agreed on the final content of the Guidelines and Animal categories. This final adopted version will be forwarded to the European Commission (EC) together with some further comments. The WG will now finalise the Common Guidance with all the details on how to perform the assessment and one example of the specific guidance for some specific types of additives. An extraordinary Plenary meeting was scheduled to be held on 14 November to discuss and possibly agree these documents before sending them to the EC.

### 6.3. Progress reports on ongoing work

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

  Draft document on the first part of the self-task mandate was tabled but not discussed due to lack of time.

### 6.4. Progress reports 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:

- **L-Lysine sulphate. Nutritional additive for all species (EFSA-Q-2005-230)**
- **Levucell SC20/Levucell SC10ME. (*Saccharomyces cerevisiae* CNCM I-1077). Zootechnical Additive for dairy goats and dairy ewes (EFSA-Q-2005-176)**

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

Applications considered valid for the start of the assessment:

- **Phyzyme XP 5000L and 5000G (6-Phytase EC3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233), a zootechnical additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fatteninig and sows (EFSA-Q-2005-080)**

  The application and the particulars related to the question on Phyzyme XP 5000L and G have been considered complete by EFSA since the 28th of September 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.

- **Biosaf ® Sc47 (*Saccharomyces cerevisiae* NCYC Sc 47), a zootechnical additive for fattening lambs (EFSA-Q-2005-149)**

  The application and the particulars related to the question on Biosaf Sc47 for fattening lambs have been considered complete by EFSA since the 30th of September 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

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

  The application and the particulars related to the question on coccidiostat Elancoban for calves for rearing and cattle for fattening have been considered complete by EFSA since the 7th of October 2005.

  The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003. A new WG has been established to deal with the evaluation of this submission.

### 7.3 Other requests received from the European Commission

The scientific co-ordinator distributed a new request from the Commission on iodine following the opinion of the FEEDAP Panel on the 25th January 2005. The terms of reference of this request have not yet been agreed upon by EFSA, and once accepted will be communicated to the Panel.

## 8. MISCELLANEOUS

A discussion paper from the Community Reference Laboratory for feed additives authorisation was distributed to the panel. The SC invited the panel members to review the document and send comments.