



## MINUTES OF THE 29<sup>TH</sup> PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 19-20 APRIL 2006)

(ADOPTED ON 23 MAY 2006)

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### PARTICIPANTS

#### Panel Members:

Arturo Anadón, Margarita Arboix Arzo, Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Coconcelli, Joop de Knecht, Gerhard Flachowsky, Anders Franklin, Anne-Katrine Lundebye Haldorsen, Ingrid Halle, Alberto Mantovani (2<sup>nd</sup> day), Kimmo Peltonen, Guido Rychen, Pascal Sanders, Pieter Wester, Wilhelm Windisch

#### Apologies

Noël Dierick, Jürgen Gropp, Alberto Mantovani (1<sup>st</sup> day), Amadeu Soares,

#### EFSA

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

#### European Commission

Marta Ponghellini (DG Health and Consumer Protection); 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 29<sup>th</sup> 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 with one modification. The point on Coxidin® (monensin sodium) for chickens and turkeys for fattening was removed from the agenda, as the discussion will be postponed because new data is expected to be submitted to EFSA in May.

### 3. DECLARATIONS OF INTEREST

No interests were declared to the items of the agenda.

#### 4. **ADOPTION OF THE DRAFT MINUTES OF THE 28<sup>TH</sup> PLENARY MEETING ON 7-9 March 2006**

The minutes of the 28<sup>th</sup> plenary meeting of the Scientific Panel held on 7-9 March 2006 were reviewed and adopted.

#### 5. **GENERAL INFORMATION FROM EFSA**

- The Scientific Co-ordinator (SC) informed the Panel that Mrs. Catherine Geslain-Lanéelle will take her post as Executive Director of EFSA on 1<sup>st</sup> July 2006.
- Regarding the renewal of the Scientific Panels of EFSA, at present comments from Member States are being collected. The Management Board will agree on the final list at the meeting to be held in May. The new Panel members will be appointed after the 1<sup>st</sup> June.
- A working group (WG) of the CONTAM Panel on cross-contamination on non-target feedingstuffs with coccidiostats has been established with the participation of several experts from the FEEDAP Panel.
- Maria Vittoria Vettori has joined the FEEDAP Team to give support to the Panel's work.

#### 6. **WORK PROGRAM**

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

##### - **Specific guidance(s) for the authorisation of feed additives**

The Rapporteur of the WG on Guidelines introduced the documents for "Specific Guidance(s)", for i) technological additives: silage additives, ii) zootechnical additives: enzymes and micro-organisms, iii) additives already authorised for use in food, iv) minor species and v) pets and other non food-producing animals. This is the last part of a series of documents detailing the specific requirements for these categories/uses of additives, as agreed by the FEEDAP Panel and which complements the "Common Guidance/Specific Guidance(s) for the establishment of the dossiers submitted with applications for authorisation of additives for use in animal nutrition", sent to the European Commission in November 2005 and January 2006.

After discussion of these specific guidance documents, the Panel agreed on their contents and now they will be sent to the European Commission.

##### - **Safety and efficacy of Sel-Plex<sup>®</sup> 2000 (EFSA-Q-2005-071)**

The Rapporteur of the WG introduced the revised draft opinion. EFSA is requested to issue an opinion on the safety and efficacy of the product Sel-Plex<sup>®</sup> 2000, selenized yeast produced by *Saccharomyces cerevisiae* CNCM I-3060.

The document was discussed with special emphasis on the sections dealing with the characterisation of the product, efficacy, safety and consumer exposure. The Panel concluded that the nutritional claim was clearly supported with data; however this was not the case of the zootechnical claim. The opinion was adopted with minor editorial changes.

##### - **Guidelines for the assessment of safety and efficacy of silage additives (EFSA-Q-2004-088)**

The Rapporteur of the WG on silage additives guidelines presented the new draft. This document was submitted for public consultation last year, and the comments received during this period contribute to the preparation the final opinion.

The new draft was reviewed in detail and after some discussion it was adopted.

- **Safety and efficacy of the enzyme preparation Phyzyme XP for chickens for fattening (EFSA-Q-2005-063)**

The Rapporteur of the WG on Enzymes introduced the new draft opinion. EFSA is requested to deliver an opinion on the efficacy and the safety of Phyzyme XP (6-phytase) for the target animals, consumer, user and environment. This product is produced by a genetically modified micro-organism. This opinion is co-adopted with the GMO Panel.<sup>1</sup> The applicant provided additional information regarding efficacy. The data presented does not support efficacy at the lowest recommended dose (250 FTU kg<sup>-1</sup>), it is only supported at 500 FTU kg<sup>-1</sup>. The product is tolerated at 7.5 times the maximum recommended dose. There are no concerns for the safety for the consumer, user or environment.

The opinion was adopted after some minor editorial changes.

- **Safety and efficacy of Bio-Feed Pro (proteinase) for chickens for fattening, piglets and pigs for fattening (EFSA-Q-2005-090)**

The Rapporteur of the WG on Enzymes introduced the new draft opinion. EFSA has been requested to deliver an opinion on the efficacy and the safety for the target animals, the consumer, the user and the environment of the product "BioFeed Pro", a preparation of proteinase produced by *Bacillus licheniformis*, as a feed additive for chickens for fattening and pigs for fattening. The document was discussed in detail.

There is not enough evidence to support efficacy at any dose for any of the target species. The product seems to be tolerated by chickens for fattening and piglets. Although there is no specific data for pigs for fattening, the Panel accepts the data on piglets to provide enough evidence to support the safety for pigs for fattening. No conclusion can be drawn on the safety for the consumer, and some concerns arise for the safety for the user.

The opinion was adopted with minor editorial changes.

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

For practical reasons, it has been decided that the final document of this self-tasking activity will be divided in two parts; one dealing with the terrestrial compartment and the other one with the aquatic compartment.

The two sub-documents were introduced by the Rapporteurs, making special emphasis on the approach taken in order to initiate the discussion and to invite the Panel members to provide further specific comments before the next plenary meeting. Some initial discussion took place. A revised document should be presented in May Plenary for clearance before launching the public consultation.

## **6.2. Progress report on ongoing work**

Not discussed

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<sup>1</sup> Date of adoption GMO Panel 28<sup>th</sup> February, 2006

## 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 a feed additive seeking authorisation under Regulation (EC) No 1831/2003 since the last plenary meeting. These applications are currently being checked for completeness:

- **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).**
- **L-Arginine. Nutritional additive for all species (EFSA-Q-2006-031)**

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

Applications considered valid for the start of the assessment:

- **Safizym X. Preparation of Endo-1,4-beta-xylanase, produced from *Tricoderma longibrachiatum*. Zootechnical for Piglets. (EFSA-Q-2005-276)**

The application and the particulars related to the question on Safizym X have been considered complete by EFSA on the 30<sup>th</sup> March 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.

- **Rovabio<sup>TM</sup> PHY AP/LC. Preparation of 3-Phytase, produced by the GMM *Penicillium funiculosum* 4.05b. Zootechnical for Chickens for fattening, laying hens, weaned piglets, fattening pigs. (EFSA-Q-2005-281)**

The application and the particulars related to the question on Safizym X have been considered complete by EFSA on the 18<sup>th</sup> April 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.

## 8. MISCELLANEOUS

A draft report on the “Variability and Uncertainty in Toxicology” from the UK Food Standards Agency has been launched to public consultation. The Panel members have received the document for commenting.