



# European Food Safety Authority

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## MINUTES OF THE 27<sup>TH</sup> PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 25-26 JANUARY 2006)

(ADOPTED ON 7 MARCH 2006)

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### **PARTICIPANTS**

#### Panel Members:

Arturo Anadón, Margarita Arboix Arzo, Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Pier Sandro Cocconcelli, Noël Dierick, Anders Franklin, Jürgen Gropp, Anne-Katrine Lundebye Haldorsen (1<sup>st</sup> day), Ingrid Halle, Alberto Mantovani, Kimmo Peltonen, Pieter Wester,

#### Apologies

Andrew Chesson, Joop de Knecht, Gerhard Flachowsky, Anne-Katrine Lundebye Haldorsen (2<sup>nd</sup> day), Guido Rychen, Pascal Sanders, Amadeu Soares, Wilhelm Windisch

#### EFSA

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

#### European Commission

Rosella E. Brozzi (DG Health and Consumer Protection); Christoph von Holst, Giuseppe Simone (DG Joint Research Centre)

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### **1. WELCOME AND APOLOGIES FOR ABSENCE**

The Vice-Chair opened the meeting and welcomed all the participants to the 27<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.

### **3. DECLARATIONS OF INTEREST**

Dr. Brufau informed that his Institute has been involved in some experiments related to the product Phytase SP 1002.

#### 4. **ADOPTION OF THE DRAFT MINUTES OF THE 26<sup>TH</sup> PLENARY MEETING ON 29-30 November 2005**

The minutes of the 26<sup>th</sup> plenary meeting of the Scientific Panel held on 29-30 November 2005 were reviewed and adopted. The adopted version of the minutes of the 25<sup>th</sup> plenary meeting was distributed to all the members.

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

- The Scientific Co-ordinator informed the Panel that, due to technical problems with the on-line applications, the deadline for the call for expressions of interest for the Scientific Committee and the Scientific Panels of the European Food Safety Authority has been extended until 17<sup>th</sup> February.
- The Community Reference Laboratory has submitted an addendum to their evaluation reports on Vevovital® (EFSA-Q-2005-007) and Formi<sup>TM</sup> LHS (EFSA-Q-2004-173).
- The Independent EFSA evaluation report is published on the EFSA website open to public consultation ([http://www.efsa.eu.int/mboard/mb\\_meetings/1276\\_en.html](http://www.efsa.eu.int/mboard/mb_meetings/1276_en.html)).
- The Scientific Co-ordinator informed the Panel that she is leaving EFSA at the end of the month. In the interim period and before a new scientific co-ordinator will be nominated, the Deputy Head of team Dr. Roncancio Peña will take the tasks of scientific co-ordination of the FEEDAP Panel.
- The provisional schedule for the Panel Plenary meetings of 2006 was presented. The dates proposed are the following: 7-9 March, 19-20 April, 14-15 June, 11-12 July, 12-13 September, 17-19 October, 21-22 November and 5-7 December.

#### 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 Working Group (WG) introduced the documents for “Specific Guidance(s)”, for technological additives other than silage additives, sensory additives (other than flavourings), nutritional additives and for zootechnical additives (other than enzymes and micro-organisms) and coccidiostats and histomonostats. These documents are complementary to the “Common Guidance for the establishment of the dossiers submitted with applications for authorisation of additives for use in animal nutrition” which was sent to the Commission in November, and detail the specific requirements for these categories of additives.

After some discussion, the contents of these specific guidance(s) were agreed by the Panel. And now these documents will be submitted to the European Commission.

###### - **Safety and efficacy of Formi<sup>TM</sup> LHS for piglets and pigs for fattening (EFSA-Q-2004-173)**

The Rapporteur of the WG introduced the modified draft opinion. EFSA is requested to deliver an opinion on the efficacy and the safety of Formi<sup>TM</sup>LHS (potassium diformate) for the target animals, consumer, user and environment. The document was reviewed in detail and the discussion focused mainly on the characterisation and the efficacy of the product. Some changes were introduced in the document.

The document will be sent to all the panel members, and the adoption should take place by written procedure.

- **Safety and efficacy of Biosaf Sc47 (*Saccharomyces cerevisiae*) for lambs (EFSA-Q-2005-149)**

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 an authorisation to use Biosaf Sc 47, which is a preparation of *Saccharomyces cerevisiae*, for lambs under the category of zootechnical additives (functional group: other zootechnical additives). After reviewing the document in detail the Panel concluded that there is evidence showing the efficacy of the product and the safety for the target animals.

The document will be sent to all the panel members, and the adoption should take place by written procedure.

- **Safety and efficacy of Aquasta (astaxanthin-rich *Phaffia rhodozyma*) for salmon and trout (EFSA-Q-2004-018)**

The Rapporteur of the WG presented the draft opinion. The Commission requested EFSA to issue an opinion on the safety and efficacy of the product AQUASTA (astaxanthin-rich *Phaffia rhodozyma* ATCC SD-5340) as a feed additive for use in trout and salmon.

The document was reviewed in detail and after some changes, the opinion was adopted.

- **Safety and efficacy of BioFeed Pro (proteinase) for chickens for fattening and pigs for fattening (EFSA-Q-2005-090)**

The Rapporteur of the WG on Enzymes introduced the 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. However, due to lack of time, only a brief discussion took place. This opinion will be discussed in detail in the next plenary.

## 6.2. Discussion a of the following scientific opinions

- **Safety and efficacy of the enzyme preparation Belfeed B1100MP and B1100ML (Endo-1,4-beta xylanase) for ducks for fattening (EFSA-Q-2005-115)**

The Rapporteur of the WG on Enzymes introduced the question and the draft opinion. The applicant is seeking an authorisation under Article 4(1) of Regulation (EC) No 1831/2003 for the use of this enzyme preparation as a zootechnical additive for ducks for fattening.

The discussion focussed mainly on the studies to demonstrate efficacy. The Panel agreed to ask the applicant for further clarification on this issue. 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 and Efficacy of Sel-Plex<sup>®</sup>2000 (EFSA-Q-2005-071)**

A member of the WG introduced the draft opinion. The Commission requested EFSA to issue an opinion on the safety and efficacy of the product Sel-Plex<sup>®</sup>2000, produced by *Saccharomyces cerevisiae* CNCM I-3060. A discussion took place on the claim made by the

applicant as a zootechnical additive. It was agreed that focus should be given to the availability of Se from Selplex, and the safety of the additive. It was also thought advisable, to introduce in the document data on the exposure of more sensitive groups.

- **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)**

Not discussed due to lack of time.

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

Not discussed due to lack of time.

## **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 five 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:

- **Safizym X (Endo-1,4-beta-xylanase). Zootechnical Additive for Piglets (EFSA-Q-2005-276).**
- **BioPlus 2B (*Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750). Others Additive for Turkeys for fattening (EFSA-Q-2005-275).**
- **Rovabio™ PHY AP/LC (3-Phytase). Zootechnical Additive for Chickens for fattening, laying hens, weaned piglets, fattening pigs. (EFSA-Q-2005-281).**
- **Biosaf® Sc47 (*Saccharomyces cerevisiae* NCYC Sc 47). Zootechnical Additive for Dairy small ruminants (EFSA-Q-2006-003).**
- **Hemicell® Feed Enzyme (β-D-Mannanase). Zootechnical Additive for Chickens for fattening (EFSA-Q-2006-004).**

### **7.2. Questions under Directive 70/524/EEC**

- **Kokcisan 120G (Salinomycin sodium) as a feed additive for chickens for fattening. (EFSA-Q-2005-006).**

An opinion for this product was adopted by the FEEDAP Panel on 7<sup>th</sup> May 2004. In this opinion it could not be concluded on the safety for the consumers due to insufficient data. The applicant has now submitted a supplementary dossier to complete the missing data and the Commission is requested EFSA to issue an opinion on the safety of this product.

### **7.3. Other questions**

- **COXIDIN® (Monensin Sodium) for Chickens for fattening and Turkeys for fattening (EFSA-Q-2006-005).**

An opinion for this product was adopted by the FEEDAP Panel on 20<sup>th</sup> October 2005. In that opinion the safety for the consumer was not established due to insufficient data. The applicant has now submitted further explanations on the data previously submitted, and the Commission has requested EFSA to assess this new submission.

- **Use of Iodine in feedingstuffs (EFSA-Q-2005-283).**

The terms of reference of this request have now been agreed upon by EFSA. EFSA shall issue an opinion on the use of iodine in feedingstuffs for dairy cows, in particular whether the currently authorised levels may undermine animal or human health, in the light of new scientific evidence.

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

Applications considered valid for the start of the assessment:

- **Biogalactosidase ( $\alpha$ -galactosidase). Zootechnical Additive for pigs for fattening (EFSA-Q-2005-224)**

The application and the particulars related to the question on Biogalactosidase ( $\alpha$ -galactosidase) have been considered complete by EFSA on the 13<sup>th</sup> December 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 horses (EFSA-Q-2005-234)**

The application and the particulars related to the question on Levucell SC20/Levucell SC10ME for horses have been considered complete by EFSA on the 7<sup>th</sup> December 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.

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

The application and the particulars related to the question on the microbial product 035 for chickens for fattening have been considered complete by EFSA on the 9<sup>th</sup> January 2006.

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**

- The Scientific Co-ordinator made an overview of the current status of the questions that are currently being assessed by the FEEDAP Panel.
- The question on “Reuteri for chickens for fattening” (EFSA-Q-2004-167) has been removed from the EFSA Register of requested questions since the applicant has withdrawn its application.