

**MINUTES OF THE 50<sup>TH</sup> PLENARY MEETING  
OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN  
ANIMAL FEED**

**(PARMA, 15-17 JULY 2008)**

**(ADOPTED ON 16 SEPTEMBER 2008)**

**PARTICIPANTS**

Panel Members

Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Bogdan Debski, Noël Dierick, Jürgen Gropp, Ingrid Halle (1<sup>st</sup> and 2<sup>nd</sup> days), Christer Hogstrand, Lubomir Leng, Anne Katrine Lundebye-Haldorsen, Miklós Mézes, Carlo Stefano Nebbia (1<sup>st</sup> and 2<sup>nd</sup> days), Walter Rambeck, Guido Rychen, Pieter Wester, Atte von Wright.

Apologies

Joop de Knecht, Anders Franklin, Ingrid Halle (3<sup>rd</sup> day), Alberto Mantovani, Carlo Stefano Nebbia (3<sup>rd</sup> day).

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Rosella Brozzi (scientific staff), Ketty Antonelli, Henni Taari, Nicola Reynolds (administrative staff).

European Commission

Marta Ponghellini (1<sup>st</sup> and 2<sup>nd</sup> days) (DG SANCO), Giuseppe Simone (1<sup>st</sup> and 2<sup>nd</sup> days) (DG JRC).

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**1. WELCOME AND APOLOGIES FOR ABSENCE**

The Chair opened the meeting and welcomed the participants to the 50<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**

Joaquim Brufau declared that his institute had performed some trials reported on the dossier on Ecobiol and therefore he did not take part in the discussion and adoption of the opinion. No other specific interests were declared relevant to the items of the agenda.

#### 4. ADOPTION OF THE DRAFT MINUTES OF THE 49<sup>TH</sup> PLENARY MEETING ON 18-19 JUNE 2008

The minutes of the 49<sup>th</sup> Plenary meeting of the Scientific Panel held on 18-19 June 2008 were reviewed and adopted.<sup>1</sup>

#### 5. WORK PROGRAM

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

- **Sorbiflore (*Lactobacillus rhamnosus* and *Lactobacillus farciminis*) for piglets (EFSA-Q-2006-062)**

The Rapporteur of the working group (WG) presented the question and the draft opinion. This question refers to an application for authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation for the product Sorbiflore to be used as a feed additive for piglets (category: zootechnical additives; functional group: gut flora stabilizers).

Following the submission of an amended report from the Community Reference Laboratory, some modifications were introduced in the draft opinion. The Panel considers that the additive should be treated as a product of fermentation and not a microbial product. The applicant has provided evidence of the efficacy and the product is considered to be safe (both micro-organisms are considered by EFSA to qualify for QPS status). Several recommendations were proposed.

The opinion was adopted.<sup>2</sup>

- **Levucell SC (*Saccharomyces cerevisiae*) for lambs (EFSA-Q-2007-139)**

The Rapporteur of the WG presented the question and the draft opinion. This question refers to an application for authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation for the product Levucell SC to be used as a feed additive for lambs (category: zootechnical additives; functional group: gut flora stabilizers).

Discussion took and based on the data provided, the FEEDAP Panel considers that the product is efficacious at the maximum recommended dose. The safety for the consumer user and environment has been previously assessed. Considering the QPS status of the active agent, no safety assessment for the target species is considered necessary.

The opinion was adopted.<sup>3</sup>

- **Self-task on functional groups under zootechnical additives (EFSA-Q-2007-173)**

Not discussed due to lack of time

- **Ecobiol (*Bacillus amyloliquefaciens*) for chickens for fattening (EFSA-Q-2007-190)**

The Rapporteur of the WG presented the question and the draft opinion. This question refers to an application for authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation for the product Ecobiol to be used as a feed additive for chickens for fattening (category: zootechnical additives; functional group: gut flora stabilizers).

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<sup>1</sup> [http://www.efsa.europa.eu/EFSA/Event\\_Meeting/feedap\\_minutes\\_49th\\_plenmeet.pdf?ssbinary=true](http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_49th_plenmeet.pdf?ssbinary=true)

<sup>2</sup> [http://www.efsa.europa.eu/EFSA/Scientific\\_Opinion/feedap\\_op\\_ej771\\_sorbiflore\\_en.pdf?ssbinary=true](http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej771_sorbiflore_en.pdf?ssbinary=true)

<sup>3</sup> [http://www.efsa.europa.eu/EFSA/Scientific\\_Opinion/feedap\\_op\\_ej772\\_levucell\\_en.pdf?ssbinary=true](http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej772_levucell_en.pdf?ssbinary=true)

Discussion took place based on the information presented. The data provided by the applicant supports efficacy of the product at the recommended dose. The active agent of this additive is a micro-organism considered by EFSA to qualify for QPS status and the applicant has provided evidence that it fulfils the qualifications imposed (e.g., absence of toxin production). Therefore, the additive is considered to be safe for the target species, consumers and environment.

The opinion was adopted.<sup>4</sup>

- **Guidance documents for the assessment of additives for use in animal nutrition in accordance with Regulation (EC) No 1831/2003 (EFSA-Q-2008-403/410)**

The FEEDAP Panel established a self-task activity to prepare a series of user-friendly guidance documents for applicants that will contribute to improve understanding of the guidelines published by the European Commission (Regulation (EC) No 429/2008). A set of guidance documents for the different categories of feed additives (EFSA-Q-2008-403) and a series of technical guidance that will provide guidance on horizontal issues are being prepared by the FEEDAP Panel.

The following guidance documents were thoroughly discussed and adopted:

- Guidance for the preparation of dossiers by categories of feed additives (EFSA-Q-2008-403). Four documents were adopted, dealing with technological, nutritional and zootechnical additives, and coccidiostats and histomonostats.
- Technical guidance: Tolerance and efficacy studies on target animals (EFSA-Q-2008-405).
- Guidance for the re-evaluation of certain additives already authorised under Directive 70/524/EEC (EFSA-Q-2008-410).

## 5.2. Discussion of the following scientific opinions

- **Biosaf Sc 47 (*Saccharomyces cerevisiae*) for dairy buffaloes (EFSA-Q-2008-010)**

Not discussed due to lack of time.

## 6. PROGRESS REPORT ON ONGOING WORK

Not discussed due to lack of time

## 7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

Not discussed due to lack of time

## 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 nine 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:

- **Natugrain Wheat TS (endo-1,4- $\beta$ -xylanase)**. Zootechnical additive for chickens for fattening and ducks (EFSA-Q-2008-418)

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<sup>4</sup> [http://www.efsa.europa.eu/EFSA/Scientific\\_Opinion/feedap\\_op\\_ej773\\_ecobiol\\_en.pdf?ssbinary=true](http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej773_ecobiol_en.pdf?ssbinary=true)

- **Ronozyme<sup>®</sup> WX (endo-1,4-β-ylanase)**. Zootechnical additive for poultry, piglets (weaned) and pigs for fattening (EFSA-Q-2008-419)
- **L-Arginine**. Nutritional additive for all species (EFSA-Q-2008-420)
- **Bactocell PA 10/ Fermaid PA 10 (*Pediococcus acidilactici*)**. Zootechnical additive for shrimps (EFSA-Q-2008-421)
- **Cylactin<sup>®</sup>/Cernivet<sup>®</sup> (*Enterococcus faecium*)**. Zootechnical additive for chickens for fattening (EFSA-Q-2008-422)
- **035 (*Bacillus subtilis*)**. Zootechnical additive for chickens for fattening (EFSA-Q-2008-423)
- **Ronozyme NP (6-phytase)**. Zootechnical additive for poultry, piglets (weaned) and pigs for fattening (EFSA-Q-2008-430)
- **Ronozyme ProAct (serine protease)**. Zootechnical additive for chickens for fattening (EFSA-Q-2008-431)
- **AveMix<sup>®</sup> (endo-1,3(4)-beta glucanase and endo-1,4-beta-xylanase and pectinase)**. Zootechnical additive for piglets (EFSA-Q-2008-432)

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

Applications considered valid for the start of the assessment:

- **Yea-Sacc (*Saccharomyces cerevisiae*)**. Zootechnical additive for horses (whole life of the animal) (EFSA-Q-2008-009) Validated on 18 June 2008.
- **Rovimix Hy D (25-hydroxycholecalciferol)** Nutritional additive for chickens and turkeys for fattening, laying hens. Poultry and pigs. (EFSA-Q-2008-014). Validated on 16 July 2008.
- **Avatec 150 G (lasalocid A sodium)**. Coccidiostat for pheasant, partridges, quails, guinea-fowl, ducks and geese/poultry (EFSA-Q-2008-080) Validated on 8 July 2008.

## 8.3. New applications under Regulation (EC) No 178/2002

- **Ractopamine** (EFSA-Q-2008-433)
- **Mintrex<sup>®</sup>Zn (Zinc chelate of hydroxy analogue of methionine)**. Nutritional additive for chickens for fattening (EFSA-Q-2008-424)
- **L-valine**. Nutritional additive for all species (EFSA-Q-2008-413)

## 8.4. New applications under Regulation (EC) No 1829/2003

- **Application for authorisation of genetically modified PT73 *Escherichia coli* (TM) for feed use (dried killed bacterial biomass)** (EFSA-Q-2008-412)

## 9. GENERAL INFORMATION FROM EFSA

The dates for the plenary meetings for 2009 have been set: 3-4 February, 3-5 March, 1-2 April, 12-14 May, 16-17 June, 7-9 July, 15-16 September, 13-15 October, 11-12 November and 8-10 December.

## 10. MISCELLANEOUS

A member of the Panel made a presentation on the opinion of the Scientific Committee on “Transparency: scientific aspects” related to EFSA-Q-2005-050. The Scientific Secretariat will summarise and send the comments made by the FEEDAP Panel to the SCAF Unit.