# MINUTES OF THE 38TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

## (PARMA, 7-8 MARCH 2007)

### (ADOPTED ON 17 APRIL 2007)

## PARTICIPANTS

Panel Members
Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Bogdan Debski, Anders Franklin, Jürgen Gropp, Ingrid Halle, Christer Hogstrand, Joop de Knecht, Lubomir Leng, Anne Katrine Lundebye-Haldorsen, Alberto Mantovani, Miklós Mézes, Carlo Stefano Nebbia, Guido Rychen, Atte von Wright, Pieter Wester.

Apologies
Noël Dierick, Walter Rambeck.

EFSA
Claudia Roncancio-Peña, Jaume Galobart, 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 38th 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 informed that his institute participated in a trial for VevoVitall® and a trial for Biosaf® Sc 47 for calves for rearing and withdrew from the discussion and vote of these two products. No other interests were declared relevant to the items of the agenda.

## 4. ADOPTION OF THE DRAFT MINUTES OF THE 37TH PLENARY MEETING ON 23-24 JANUARY 2007

The minutes of the 37th plenary meeting of the Scientific Panel held on 23-24 January 2007 were reviewed and adopted.[1]

## 5. WORK PROGRAM

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

- **Safety and efficacy of Toyocerin® (*Bacillus cereus*) for sows (EFSA-Q-2006-037)**

  The Rapporteur of the Working Group (WG) introduced the question and 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 authorisation of the product Toyocerin® to be used as a zootechnical feed additive (functional group: gut flora stabilizers). The additive Toyocerin® is a preparation of *Bacillus cereus* var. Toyoi and it is already authorised for its use in piglets up to four months, pigs for fattening, sows from one week prior to farrowing until weaning, cattle for fattening, chickens for fattening and rabbits for fattening (E 1701). The applicant is requesting an extension of use of the additive in sows from service until weaning.

  The applicant has provided four new studies which show that use of Toyocerin® over the entire cycle produces significant benefits to the piglets. However, the FEEDAP Panel is unable to assess the additional benefits that might be provided by use of the additive over the entire reproductive cycle compared to the currently authorised period.

  The opinion was adopted after some editorial changes.[2]

- **Safety and efficacy of VevoVitall® (benzoic acid) for pigs for fattening (EFSA-Q-2006-056)**

  The Rapporteur of the WG introduced the question and 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 of the product VevoVitall®, consisting on benzoic acid, to be used as a zootechnical additive (functional groups: "substances which favourably affect the environment" and "other zootechnical additives: pH decrease") for pigs for fattening.

  The applicant has provided evidence that the use of the product causes a decrease in urinary pH of pigs for fattening. However, since the relation between urinary pH and reduced ammonia emission is not adequately established, the FEEDAP Panel can not conclude on the efficacy of benzoic acid to reduce the ammonia emission. Two tolerance studies provided evidence that the highest recommended dose of the product is safe for pigs for fattening, with a margin of safety of less than 1.5.

  The opinion was adopted.[3]

[1] http://www.efsa.europa.eu/en/science/feedap/feedap_meetings/feedap_agenda_37th_plenmeet.html
[2] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej458_toyocerin_sows.html
[3] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej457_vevovitall_pigs.html

- **Safety and efficacy of Biosaf® Sc 47 (*Saccharomyces cerevisiae*) for calves for rearing (EFSA-Q-2006-067)**

  The Rapporteur of the WG introduced the question and 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 authorisation of the product Biosaf® Sc 47 to be used as a zootechnical feed additive (functional group: gut flora stabilizers) in calves for rearing. The additive Biosaf® Sc 47 is a preparation of *Saccharomyces cerevisiae* which is already authorised for its use in cattle for fattening, dairy cows, rabbits for fattening, sows, piglets, lambs for fattening, horses, dairy goats and dairy sheep.

  The applicant presented four studies in calves for rearing to support efficacy. However, the extensive therapeutic/preventive treatments to reduce morbidity in the experimental animals in three of the trials, does not allow the FEEDAP Panel to reach a conclusion on the efficacy of Biosaf® Sc 47 for the target species. This product appears to be safe for calves for rearing.

  The opinion was adopted.

- **Guidance document on environmental risk assessment**

  The Rapporteur of the WG introduced the document on the terrestrial compartment and highlighted the changes introduced in the document after taking into consideration the comments received during the public consultation. Extensive discussion on the methodology proposed to refine the Predicted Environmental Concentration took place and after some minor changes the opinion was adopted by the Panel.

- **Safety and efficacy of L-Arginine for all animal species (EFSA-Q-2005-043)**

  Not discussed due to lack of time.

## 6. PROGRESS REPORT 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:

- **Polysaccharide complex of copper, iron, manganese and zinc (Polysaccharide Complexed Trace Minerals).** Nutritional additive for all species **(EFSA-Q-2007-051)**
- **Guanidinoacetic acid (CreAmino™).** Nutritional additive for chickens and turkeys **(EFSA-Q-2007-050)**

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

Applications considered valid for the start of the assessment:

- **Lantharenol® (lanthanum carbonate octahydrate).** Zootechnical additive for cats **(EFSA-Q-2006-317)**

  The application and the particulars related to the question on Lantharenol® have been considered valid by EFSA on the 6th March 2007.

The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

- **Safizym X (endo-1,4-beta-xylanase).** Zootechnical additive for ducks **(EFSA-Q-2006-320)**

  The application and the particulars related to the question on Safizym X for ducks have been considered valid by EFSA on the 2nd March 2007.

  The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003. This application will be dealt by the WG on Enzymes.

- **Bonvital (*Enterococcus faecium*).** Zootechnical additive for sows **(EFSA-Q-2007-033)**

  The application and the particulars related to the question on Bonvital for sows have been considered valid by EFSA on the 5th March 2007.

  The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003. This application will be dealt by the WG on Micro-organisms.

### 7.3. New questions under Regulation (EC) No 178/2002

- **Natuphos® STIPT (3-phytase). Safety for laying hens and turkeys (EFSA-Q-2007-049).**

  The FEEDAP and GMO Panels issued an opinion on the safety and efficacy of the enzyme preparation Natuphos® (3-phytase) produced by a genetically modified strain of *Aspergillus niger*.[4] In that opinion, the Panel could not reach a conclusion on safety for the target species laying hens, turkeys for fattening and sows. The applicant has now submitted new tolerance studies for laying hens and turkeys for fattening. This question will be dealt by the WG on Enzymes.

  The deadline proposed by the European Commission is May 2007.

## 8. GENERAL INFORMATION FROM EFSA

- The Secretariat informed the Panel on the technical hearings held during the last two months.
- A WG of the Standing Committee on Animal Health and Food Chain took place on 29th January to discuss the new guidelines for the assessment of feed additives. Some members of the Panel and the Scientific Secretariat of EFSA attended to this meeting and reported back to the Panel.
- The representative of the Community Reference Laboratory (CRL) for feed additives authorisation announced the next CRL workshop that will take place in Geel (Belgium) on 7-8 June, and to which EFSA is invited to attend.

## 9. MISCELLANEOUS

- The Chair informed the Panel about the latest progress and the current status related with the revision of the daily allowances and indemnities. The Chair reported back on the discussion held at the meeting of the Scientific Committee in which the Executive Director, Ms. Geslain-Lanéelle was present. The Executive Director informed that EFSA is obliged to

[4] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/1568.html

follow the financial rules for committees and/or scientific panels established by the European Commission. Modifications to these rules shall be done directly by the Management Board, and this process needs some time.

However, immediate actions were already taken by the Executive Director. Some of these concern derogations to cover the costs of private car parking and/or taxis when no easy public transport is available and the possibility of flying using some flexible tickets.

The Panel members recognised and thanked the efforts undertaken by the Executive Director to positively respond to the concerns raised by the FEEDAP Panel.

The Management Board will include this issue for discussion during the meeting that will be held on 27 March, and the Panel is waiting for the outcome of the discussion.