

**MINUTES OF THE 46TH PLENARY MEETING
OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN
ANIMAL FEED**

(BARCELONA, 5-6 MARCH 2008)

(ADOPTED ON 15 APRIL 2008)

PARTICIPANTS

Panel Members

Georges Bories, Paul Brantom, Joaquim Brufau de Barberà (1st day), Andrew Chesson, Pier Sandro Cocconcelli, Bogdan Debski, Joop de Knecht (1st day), Noël Dierick, Anders Franklin, Jürgen Gropp, Ingrid Halle, Christer Hogstrand, Lubomir Leng, Anne Katrine Lundebye-Haldorsen, Alberto Mantovani, Miklós Mézes, Walter Rambeck, Guido Rychen, Pieter Wester, Atte von Wright.

Apologies

Joaquim Brufau de Barberà (2nd day), Joop de Knecht (2nd day), Carlo Stefano Nebbia.

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Gloria López-Gálvez, Rosella Brozzi (scientific staff), Ketty Antonelli, (administrative staff).

European Commission

Marta Ponghellini, Miguel Angel Granero (DG SANCO), Giuseppe Simone, Piotr Robouch (DG JRC).

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 46th 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. Joaquim Brufau declared that his institute had performed some studies for the dossier on Ronozyme NP. No other interests were declared relevant to the items of the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 45TH PLENARY MEETING ON 12-13 DECEMBER 2007

The minutes of the 45th Plenary meeting of the Scientific Panel held on 12-13 December 2007 were reviewed and adopted.¹

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Compatibility of zootechnical microbial additives with other additives showing antimicrobial activity (EFSA-Q-2007-104)**

The Rapporteur of the working group (WG) introduced the question and the draft opinion. The FEEDAP Panel has been requested to produce a guidance document on the assessment of the compatibility between zootechnical microbial additives and substances showing an antimicrobial effect (e.g., coccidiostats, organic acids).

A first draft was already discussed and agreed by the Panel and was submitted to public consultation in October 2007. Several comments were received from stakeholders during the consultation period, which were considered in the preparation of the new draft.

The purpose of this Guidance is not to define the conditions under which microbial additives can or might be used in conjunction with other additives with antimicrobial activity, but to suggest how compatibility should be assessed should the need arise. The FEEDAP Panel proposes a stepwise approach to establish compatibility in which an *in vitro* screening is used to exclude cases where incompatibility is very unlikely, reserving *in vivo* studies for situations where *in vitro* results suggest that an incompatibility may exist.

After some discussion, the document was adopted.²

- **Mintrex[®] Mn (Manganese chelate of hydroxy analogue of methionine) for all species (EFSA-Q-2007-094)**

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 manganese chelate with the hydroxy analogue of methionine (Mintrex[®]Mn), to be used as a feed additive for all species (category: nutritional additives; functional group: compounds of trace elements).

The discussion focussed mainly in the sections on efficacy, tolerance, tissue/products deposition and consumer exposure. Major editorial changes were proposed, as well as the refinement of the conclusions, based on the discussion held.

It was agreed that the FEEDAP secretariat would submit the draft opinion -including the changes made during the Plenary meeting- for written adoption.

- **Mintrex[®] Cu (Copper chelate of hydroxy analogue of methionine) for all species (EFSA-Q-2007-097)**

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 copper chelate with

¹ http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_45th_plenmeet.pdf

² http://www.efsa.europa.eu/EFSA/Scientific_Document/feedap_guidance_ej658_compatibility_en,0.pdf

the hydroxy analogue of methionine (Mintrex[®]Cu) to be used as a feed additive for all species (category: nutritional additives; functional group: compounds of trace elements).

Only a general discussion took place and it was agreed that the draft opinion would be reviewed in the light of changes made to the Mintrex[®]Mn and would be presented again for discussion and possible adoption in the next Plenary meeting.

- **Mintrex[®]Zn (Zinc chelate of hydroxy analogue of methionine) for all species (EFSA-Q-2007-098)**

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 zinc chelate with the hydroxy analogue of methionine (Mintrex[®]Zn), consisting of a, to be used as a feed additive for all species (category: nutritional additives; functional group: compounds of trace elements).

Only a general discussion took place and it was agreed that the draft opinion would be reviewed in the light of changes made to the Mintrex[®]Mn and would be presented again for discussion and possible adoption in the next Plenary meeting.

5.2. Discussion of the following scientific opinions

- **Safety and efficacy of Ronozyme NP (6-phytase) for chickens for fattening (EFSA-Q-2007-133)**

Not discussed due to lack of time.

6. PROGRESS REPORT ON ONGOING WORK

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 eight 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:

- **Roxazyme[®] G2 G/L (endo-1,4- β -glucanase, endo-1,(3)4- β -glucanase and endo-1,4- β -xylanase).** Zootechnical additive for chickens and turkeys for fattening, laying hens, ducks and piglets (weaned) and poultry (EFSA-Q-2007-185)
- **Bactocell PA 10 or Fermaid PA 10 (*Pediococcus acidilactici*).** Zootechnical additive for fish (EFSA-Q-2007-205)
- **Yea-Sacc[®] (*Saccharomyces cerevisiae*).** Zootechnical additive for horses (EFSA-Q-2008-009)
- **Biosaf Sc47 (*Saccharomyces cerevisiae*).** Zootechnical additive for dairy buffaloes (EFSA-Q-2008-010)
- **Clinacox 0.5% (diclazuril).** Coccidiostat for rabbits for fattening and breeding (EFSA-Q-2008-011)
- **Natugrain[®] TS (endo-1,4- β -xylanase, endo-1,4- β -glucanase).** Zootechnical additive for piglets (weaned), chickens and turkeys for fattening, laying hens and ducks (EFSA-Q-2008-013)

- **Rovimix Hy D[®] (25-hydroxycholecalciferol)**. Nutritional additive for chickens and turkeys for fattening, laying hens. Poultry and pigs (EFSA-Q-2008-014)
- **BioKey[®] Zinc (Zinc chelate of amino acids hydrate)**. Nutritional additive for all species (EFSA-Q-2008-015)

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

Applications considered valid for the start of the assessment:

- **Levucell SC (*Saccharomyces cerevisiae*)**. Zootechnical additive for lambs for fattening (EFSA-Q-2007-139).

The application and the particulars related to this question have been considered valid by EFSA on the 22 January 2008. The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

- **Elancoban[®] 100G/200G (Monensin sodium) Coccidiostat for Chickens for fattening, turkeys and chickens reared for laying** (EFSA-Q-2007-140).

The application and the particulars related to this question have been considered valid by EFSA on the 13 February 2008.

7.3. Self-task

- **Update of breakpoints for the assessment of antimicrobial resistance in the evaluation of feed additives** (EFSA-Q-2008-004)

In May 2005, the FEEDAP Panel adopted an opinion on the updating of the criteria used in the assessment of bacteria for resistance to antibiotics of human or veterinary importance.³ Considering that significant advances have been made in the research of antibiotic resistance in the last few years, the FEEDAP Panel is requested to revise its former opinion considering the current body of knowledge. This revision should focus mainly on the microbiological breakpoints categorising bacteria as resistant to a given antibiotic.

The proposed deadline for this opinion is July 2008.

8. GENERAL INFORMATION FROM EFSA

Not discussed due to lack of time.

9. MISCELLANEOUS

The Plenary meeting of April will be extended for one day. It will now take place on 15-17 April 2008.

³ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the updating of the criteria used in the assessment of bacteria for resistance to antibiotics of human and veterinary importance, adopted on 25 May 2005. http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej223_antibiotics_en1.0.pdf