

**MINUTES OF THE 51ST PLENARY MEETING
OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN
ANIMAL FEED**

(PARMA, 16-17 SEPTEMBER 2008)

(ADOPTED ON 21 OCTOBER 2008)

PARTICIPANTS

Panel Members

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

Apologies

Joaquim Brufau de Barberà, Noël Dierick.

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Maria Vittoria Vettori, Gloria López-Gálvez (scientific staff), Nicola Reynolds (administrative staff).

European Commission

Marta Ponghellini (1st day) (DG SANCO).

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 51st Plenary meeting of the FEEDAP Panel.

Members not able to attend the meeting had sent their apologies (see under participants).

The Chair informed the Panel that Prof. Anders Franklin resigned as a member of the FEEDAP Panel as of 9th August 2008. The Chair and the Panel members, as well as the secretariat acknowledged the work that Prof. Franklin performed during these last five years as a member of the FEEDAP Panel.

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

No specific interests were declared relevant to the items of the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 50TH PLENARY MEETING ON 15-17 JULY 2008

The minutes of the 50th Plenary meeting of the Scientific Panel held on 15-17 July 2008 were reviewed and adopted.¹

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Cycostat[®] 66G (robenidine hydrochloride) for chickens for fattening and turkeys (EFSA-Q-2007-180)**

The Rapporteur of the WG presented the question and the draft opinion. This question refers to an application for modification of the authorisation of a feed additive under Article 13(3) of Regulation (EC) No 1831/2003. The applicant proposed the addition of MRLs in chickens for fattening and turkeys to the current authorisation of the additive Cycostat[®] 66G and the adaptation of the withdrawal period if applicable.

This opinion was already discussed during the Plenary meeting of May. At that time, the report from the CRL was not yet available and the commenting period for Member States (MS) was still open. After reception and consideration of both the CRL report and the comments of the MS, the opinion was presented to the Panel for possible adoption.

The FEEDAP Panel considers robenidine as the marker residue in chickens and turkeys. Consumer exposure from the consumption of tissues from chickens administered robenidine at the maximum authorised dose represents without withdrawal only a limited fraction of the ADI. Therefore, based on safety considerations, the FEEDAP Panel does not see the necessity for setting a withdrawal period for chickens for fattening and consequently of MRLs. The same conclusion applies to turkeys for fattening. However, the FEEDAP Panel proposed MRLs in case they are needed for control purposes.

Off-flavours were observed in edible tissues of chickens for fattening until three days after withdrawal, despite the lack of data for turkey products, the FEEDAP Panel considers that chickens and turkeys should be regarded similarly. As a consequence, the FEEDAP Panel proposes a five-day withdrawal period for chickens and turkeys for fattening, to avoid off-flavours in edible tissues from poultry treated with robenidine. To guarantee the quality of the product, a Maximum (food product) Processing Compatible Residue (MPCR) should be introduced which would be considerably lower than the MRLs. Due to the insufficient sensitivity of the available method of analysis and the absence of data at five-day withdrawal, the FEEDAP Panel cannot propose such an MPCR for robenidine.

The opinion was adopted.²

- **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 have been prepared by the FEEDAP Panel.

¹ http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_50th_plenmeet_en.pdf?ssbinary=true

² http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej798_cycostat_66g_en.3.pdf?ssbinary=true

The following guidance documents were thoroughly discussed and adopted:

- Guidance for the preparation of dossiers by categories of feed additives (EFSA-Q-2008-403). Sensory additives (Part 1 – colourants).
- Technical guidance: Additives already authorised for use in food (EFSA-Q-2008-404).
- Technical guidance: Consumer safety (EFSA-Q-2008-406).
- Technical guidance: User safety (EFSA-Q-2008-407).
- Technical guidance: Extrapolation of data from major species to minor species (EFSA-Q-2008-409).

The adopted guidance documents are available on the website.³

5.2. Discussion of the following scientific opinions

- **Advastat (acarbose) for cattle for fattening and dairy cows (EFSA-Q-2007-172)**

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 three 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:

- **Bioimin® IMB 52 (*Enterococcus faecium*)**. Zootechnical additive for piglets (EFSA-Q-2008-471)
- **Bacillus Subtilis PB6 (*Bacillus subtilis*)**. Zootechnical additive for chickens for fattening (EFSA-Q-2008-473)
- **Maxiban® (Narasin 80 g, Nicarbazin 80 g)**. Coccidiostat for chickens for fattening (EFSA-Q-2008-474)

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

Applications considered valid for the start of the assessment:

- **Phyzyme XP 10000 TPT/L (*Schizosaccharomyces pombe*)**. Zootechnical additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening, sows (EFSA-Q-2008-272). Validated on 1 August 2008.
- **Toyocerin (*Bacillus cereus* var. *toyoi*)**. Zootechnical additive for rabbit breeding does (EFSA-Q-2008-287) Validated on 24 July 2008.

³ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_feedap_technical_guidance.htm

- **Bonvital (*Enterococcus faecium*)**. Zootechnical additive for chickens for fattening (EFSA-Q-2008-289) Validated on 18 July 2008.
- **Biosprint (*Saccharomyces cerevisiae*)**. Zootechnical additive for sows (EFSA-Q-2008-302). Validated on 18 August 2008.
- **AveMix[®] XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase)**. Zootechnical additive for chickens for fattening (EFSA-Q-2008-308). Validated on 31 July 2008.
- **Bactocell PA 10 or Fermaid PA 10 (*Pediococcus acidilactici*)**. Zootechnical additive for shrimps (EFSA-Q-2008-421). Validated on 5 August 2008.
- **035 (*Bacillus subtilis*)**. Compatibility with decoquinate and narasin/nicarbazin in feed for (EFSA-Q-2008-423). Validated on 8 September 2008.

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

- **Levucell SC 20 (*Saccharomyces cerevisiae*)**. Zootechnical additive for horses (EFSA-Q-2008-472).

9. GENERAL INFORMATION FROM EFSA

A member of the scientific secretariat made a short presentation on the Expert Survey Project.

10. MISCELLANEOUS

- A member of the Panel made an update on the current status of the opinion of the Scientific Committee on “Transparency: scientific aspects” related to EFSA-Q-2005-050.
- Three new members have joined the FEEDAP Team: Matteo Innocenti, Orsolya Holczknecht and Nikola Burelli.