

MINUTES OF THE 48TH PLENARY MEETING

OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 20-21 MAY 2008)

(ADOPTED ON 18 JUNE 2008)

PARTICIPANTS

Panel Members

Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Bogdan Debski, Joop de Knecht (2nd day), Noël Dierick, Jürgen Gropp, Ingrid Halle, Christer Hogstrand, Lubomir Leng, Anne Katrine Lundebye-Haldorsen, Alberto Mantovani (2nd day), Miklós Mézes, Carlo Stefano Nebbia (2nd day), Guido Rychen (2nd day), Pieter Wester, Atte von Wright.

Apologies

Joop de Knecht (1st day), Anders Franklin, Alberto Mantovani (1st day), Carlo Stefano Nebbia (1st day), Walter Rambeck, Guido Rychen (1st day).

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Maria Vittoria Vettori, Montserrat Anguita (scientific staff), Ketty Antonelli (administrative staff).

European Commission

Marta Ponghellini, Taina Satëri (DG SANCO), Christoph von Holst (1st day) (DG JRC).

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 48th 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 dossiers on Econase XT and Ronozyme NP and he did not take part in the discussions/adoption of the respective opinions. No other specific interests were declared relevant to the items of the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 47TH PLENARY MEETING ON 15-16 APRIL 2008

The minutes of the 47th Plenary meeting of the Scientific Panel held on 15-16 April 2008 were reviewed and adopted.¹

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Econase[®] XT L/P (endo-1,4-beta-xylanase) for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding and piglets (weaned) (EFSA-Q-2007-120)**

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 Econase[®] XT P/L to be used as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and piglets (weaned) (category: zootechnical additives; functional group: digestibility enhancers).

This product is produced by a genetically modified micro-organism, and the safety aspects of the genetic modification were assessed by the GMO Panel.²

The discussion focussed mainly on the efficacy and tolerance sections. The Panel concluded that there is evidence to support the efficacy in the target species for which a request was made. It was also concluded that the product is safe at the proposed conditions of use for the same target species, but some doubts were raised on the margin of safety for chickens for fattening/reared for laying. No special concerns were raised for the safety for the consumer, user or the environment.

The opinion was adopted.³

5.2. Discussion of the following scientific opinions

- **Ronozyme[®] NP (6-phytase) for chickens for fattening (EFSA-Q-2007-133)**

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 Ronozyme[®] NP to be used as a feed additive for chickens for fattening (category: zootechnical additives; functional groups: digestibility enhancer, substances which favourably affects the environment).

This product is produced by a genetically modified micro-organism, and is currently being assessed by the GMO Panel with regards to the safety of the genetic modification.

This opinion was already discussed in the Plenary of December 2007, in which several suggestions for modification were made. The Panel reviewed the modifications in the document. The opinion will be presented again for adoption once the safety aspects of the genetic modification are addressed by the GMO Panel.

¹ http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_47th_plenmeet,0.pdf

² Adopted by the GMO Panel on 16 April 2008.

³ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178716685437.htm

- **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.

A first discussion took place. The opinion will be presented to the Plenary again, once the CRL report has been delivered and the commenting period from the Member States is closed.

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

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 six 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:

- **Toyocerin (*Bacillus cereus* var. *toyoi*)** Zootechnical additive for rabbits breeding does (EFSA-Q-2008-287).
- **Xylanase (Endo-1,4-beta-xylanase).** Zootechnical additive for turkeys (EFSA-Q-2008-288).
- **Bonvital (*Enterococcus faecium*).** Zootechnical additive for chickens for fattening (EFSA-Q-2008-289).
- **Biosprint (*Saccharomyces cerevisiae*).** Zootechnical additive for sows (EFSA-Q-2008-302).
- **Miya-Gold® S (*Clostridium butyricum*).** Zootechnical additive for chickens for fattening (EFSA-Q-2008-303).
- **AveMix® XG 10 (Endo-1,4- β -xylanase and endo-1,3(4)- β -glucanase).** Zootechnical additive for chickens for fattening (EFSA-Q-2008-308).

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

Applications considered valid for the start of the assessment:

- **Cycostat® 66G (Robenidine hydrochloride).** Coccidiostat for chickens for fattening and turkeys (EFSA-Q-2007-180)

The application and the particulars related to this question have been considered valid by EFSA on the 13 May 2008. A first discussion took place (see 5.2).

- **Biosaf Sc47 (*Saccharomyces cerevisiae*).** Zootechnical additive for dairy buffaloes (EFSA-Q-2008-010)

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

- **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).

The application and the particulars related to this question have been considered valid by EFSA on the 16 May 2008. The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

8. GENERAL INFORMATION FROM EFSA

The director of the Risk Assessment Directorate, Riitta Maijala attended the plenary meeting to inform the Panel about the internal/external review of the scientific opinions and the new IT tool to fill in the declarations of interest.

9. MISCELLANEOUS

- Several members of the Panel reported on the outcome of two meetings with stakeholders. The first took place in Ghent (Belgium) on 23 April and was organised by the International Association of the European Manufacturers of Major, Trace and Specific Feed Mineral Materials (EMFEMA). The second was held in London on 25 April, organised by EFSA and hosted by the UK Food Standards Agency on the assessment of silage additives. Both meetings were intended to provide guidance on the assessment of additives based on the new guidelines adopted by the EC.
- One member of the Panel reported on the work that has been done so far in the WG of the Scientific Committee on nanotechnology.
- The EC representative presented a table with the legislative acts that have been adopted following the opinion of the FEEDAP Panel during the last 2 years.
- The plenary meetings of October and December have been extended by an extra day. The new dates are 21-23 October and 9-11 December.