MINUTES OF THE 41ST PLENARY MEETING

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

(PARMA, 10-12 JULY 2007)

(ADOPTED ON 18 SEPTEMBER 2007)

PARTICIPANTS

Panel Members

Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli (1st and 3rd days), Bogdan Debski, Joop de Knecht (1st and 2nd days), Jürgen Gropp, Ingrid Halle (1st and 2nd days), Christer Hogstrand, Lubomir Leng, Anne Katrine Lundebye-Haldorsen, Miklós Mézes, Carlo Stefano Nebbia (1st and 2nd days), Walter Rambeck, Guido Rychen, Atte von Wright, Pieter Wester.

Apologies

Pier Sandro Cocconcelli (2nd day), Joop de Knecht (3rd day), Noël Dierick, Anders Franklin, Ingrid Halle (3rd day), Alberto Mantovani, Carlo Stefano Nebbia (3rd day).

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Lucilla Gregoretti (scientific staff), Ketty Antonelli, Caroline Baltus, Anthony Hogan (administrative staff).

European Commission

Marta Ponghellini (2nd and 3rd days), Taina Säteri (1st day) (DG SANCO), Giuseppe Simone (2nd and 3rd days) (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 41st 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 with the inclusion of the questions on Ronozyme P for ducks and Safizym X for ducks.

3. DECLARATIONS OF INTEREST

The annual declarations of interest were filled in by the experts, which will be published in the web.

Dr. Paul Brantom declared that he had provided consultancy services to Danisco regarding the dossier on Danisco Xylanase. Prof. Jürgen Gropp declared that he had provided consultancy services to Bayer regarding the dossier on Lantharenol® for cats. These experts were excluded from the discussion of the respective products. No other interests were declared relevant to the items of the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 40TH PLENARY MEETING ON 12-14 JUNE 2007

The minutes of the 40th plenary meeting of the Scientific Panel held on 12-14 June 2007 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of Ronozyme P (6-phytase) for ducks for fattening (EFSA-Q-2006-060)**

  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 Ronozyme P to be used as a zootechnical feed additive (functional group: digestibility enhancers and additives which favourably affect the environment) in ducks. This product is already authorised for chickens for fattening, turkeys for fattening, laying hens, piglets, pigs for fattening and sows, and provisionally authorised for salmonids.

  The Panel considers that there is enough evidence to support the efficacy of the product at the lowest recommended dose for ducks for fattening. The data on tolerance showed that the product is safe for the target species.

  The opinion was adopted.[2]

- **Safety and efficacy of Safizym X (endo-1,4-beta-xylanase) for ducks (EFSA-Q-2006-320)**

  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 Safizym X to be used as a zootechnical feed additive (functional group: other zootechnical additives) in ducks. This product is already authorised for chickens for fattening, turkeys for fattening and laying hens.

  The Panel considers that there is enough evidence to support the efficacy of the product at the lowest recommended dose for ducks for fattening. The data on tolerance showed that the product is safe for the target species.

  The opinion was adopted.[3]

- **Safety and efficacy of Bonvital (*Enterococcus faecium*) for sows (EFSA-Q-2007-033)**

  The Rapporteur of the WG introduced the question and the draft opinion. This question refers to an application for authorisation of a feed additive under Article 4(1) of Regulation

[1] http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_40th_plenmeet.pdf
[2] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej519_ronozymep_ducks_en,0.pdf
[3] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej520_safizym_ducks_en,2.pdf

(EC) No 1831/2003. The applicant is seeking authorisation of the product Bonvital as a zootechnical additive for sows (functional group: gut flora stabilisers). This product is authorised for use in piglets and pigs for fattening, and provisionally authorised for sows from 25 days before farrowing and during lactation and for chickens for fattening.

The applicant has provided six studies to support efficacy of this product. Evidence was provided that Bonvital when given at the minimum recommended dose (0.5×10^9 CFU kg^{-1} complete feed) to sows has a positive effect on the survival and growth of piglets. However, there is no evidence to suggest that these benefits require the use of the product for the full reproductive cycle of sows. The tolerance study presented supports the safety of the product when given at the maximum recommended dose.

The opinion was adopted.[4]

- **Safety and efficacy of Vitalys® (L-lysine sulphate) for all species (EFSA-Q-2005-230)**

The Rapporteur of the WG introduced 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 of the product Vitalys® to be used as a nutritional additive (functional group: amino acids, their salts and analogues) for all animal species.

The new version of the opinion, modified according to the recommendations made by the Panel during the last plenary, was presented. The FEEDAP Panel considers Vitalys® to be a source of lysine for all animal species. Although nothing in the data provided on the use of Vitalys® in pigs and poultry suggested that Vitalys® would pose a risk when used to satisfy lysine requirements, the results from the 90-day rat study, in which adverse effects were observed and not satisfactorily explained, does raise concerns for target animal safety. For the same reason, the FEEDAP Panel is not in a position to conclude on the safety of Vitalys® for the consumer. Some concerns were also expressed regarding the safety for the user. No risks are expected for the environment deriving from the use of Vitalys®.

The opinion was adopted after some editorial modifications.[5]

- **Safety of Zeolite A (sodium alimunosilicate, synthetic) for the reduction of risk of milk fever in dairy cows (EFSA-Q-2006-184)**

A member of the WG introduced the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety for the target species and the consumer of the product Zeolite A (sodium aluminosilicate, synthetic) for the reduction of risk of milk fever in dairy cows.

Data from the current dossier confirm the conclusion reached by the FEEDAP Panel in a previous opinion,[6] that Zeolite has the potential to reduce the risk of milk fever, particularly for older cows with three or more calvings. Some negative effects have been observed in cows treated with high doses of Zeolite, however they do not last in time and do not lead to safety concern for dairy cows, if the appropriate levels of Zeolite are used. The Panel also considers the use of Zeolite in dry cows will not increase the consumer exposure to aluminium.

[4] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej521_bonvital_sows_en,1.pdf
[5] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej522_vitalys_asp_en.pdf
[6] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/745.html

The opinion was adopted.[7]

- **Safety and efficacy of Lantharenol® (lanthanum carbonate octahydrate) for cats (EFSA-Q-2006-317)**

  The Rapporteur presented the question and the draft opinion. This is an application under Article 4 of Regulation 1831/2003. The applicant is requesting authorisation of the product Lantharenol® to be used as zootechnical additive (functional group: other zootechnical additives) for adult cats to restrict the intestinal absorption of phosphorus. An initial discussion took place and the opinion will be presented to the next Plenary for adoption after reception and evaluation of comments from Member States and the CRL report.

5.2. Discussion of the following scientific opinions

- **Safety and efficacy of Danisco Xylanase G/L (endo-1,4-beta-xylanase) for chickens for fattening, laying hens and ducks (EFSA-Q-2006-137)**

  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 four 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:

- **Danisco Xylanase G/L (endo-1,4-beta-xylanase).** Zootechnical additive for turkeys for fattening (EFSA-Q-2007-109)
- **Maxiban 160 G (narasin and nicarbazin).** Coccidiostats for chickens for fattening (EFSA-Q-2007-111)
- **Avizyme 1505 (endo-1,4-beta-xylanase, subtilisin, alpha-amylase).** Zootechnical additive for turkeys for fattening (EFSA-Q-2007-112)
- **Econase XT L/P (beta-xylanase).** Zootechnical additive for chickens for fattening/reared for laying, turkeys for fattening/reared for breeding and piglets (weaned) (EFSA-Q-2007-120)

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

Applications considered valid for the start of the assessment:

- **Avizyme 1505 (endo-1,4-beta-xylanase, subtilisin, alpha-amylase).** Zootechnical additive for chickens for fattening, laying hens and ducks **(EFSA-Q-2007-020)**

  The application and the particulars related to the question on Avizyme 1505 have been considered valid by EFSA on the 10th July 2007.

[7] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej523_zeolite_en,2.pdf

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 GMO Panel has received two requests for the assessment of biomass produced from genetically modified micro-organisms. A WG has been set by the FEEDAP Panel to deal with the safety of the product for the target species and humans.
- The dates for the Plenary meetings for 2008 were agreed by the Panel.
- Two new scientific staff have been recruited in the FEEDAP Team: Anthony Hogan and Diana Herold, who is a Seconded National Expert from Croatia.

9. MISCELLANEOUS

- The Executive Director of EFSA, Ms. Catherine Geslain-Lanéelle, gave a short presentation to the Panel summarising EFSA's achievements during the last year and the new challenges for the future. She also acknowledged the workload that the FEEDAP Panel has and thanked the Panel members for their dedication and efforts.
- A short presentation regarding the expert compensation was given by Ms. Mari Varho from the finance department.
- A WG has been set to define the guidance documents that the Panel will need to draft once the Guidelines for the assessment of additives for use in animal nutrition are adopted by the EC.
- The new interface of the EFSAnet was presented into more detail to the Panel experts.