MINUTES OF THE 44TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(BRUSSELS, 22 NOVEMBER 2007)

(ADOPTED ON 12 DECEMBER 2007)

PARTICIPANTS

Panel Members
Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Bogdan Debski, Joop de Knecht, 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
Carlo Stefano Nebbia

EFSA
Claudia Roncancio-Peña, Jaume Galobart (scientific staff), Virginia Spurio-Salvi (administrative staff).

European Commission
Marta Ponghellini, Taina Säteri (DG SANCO), Giuseppe Simone (DG JRC).

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 44th 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 after the inclusion of an item regarding the discussion of the scientific approach to be taken when an additive is authorised for a pet species and an second application requests extension to another pet species.

3. DECLARATIONS OF INTEREST

Dr. Paul Brantom declared that he had provided consultancy services to Danisco regarding the dossier on Danisco Xylanase and did not take part in the discussion relative to this product. No other interests were declared relevant to the items of the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 43RD PLENARY MEETING ON 17-18 OCTOBER 2007

The minutes of the 43rd Plenary meeting of the Scientific Panel held on 17-18 October 2007 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of Biosaf Sc 47 (*Saccharomyces cerevisiae*) for pigs for fattening (EFSA-Q-2007-104)**

  The Rapporteur of the working group (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 Biosaf Sc 47 as a zootechnical additive (functional group, other zootechnical additives) for pigs for fattening. This product has been authorised for use in several target species.

  This opinion was already discussed during the Plenary meeting of October, where some modifications were suggested. A revised draft opinion has been presented. The discussion focussed mainly on the efficacy trials presented. The FEEDAP Panel considers that there is evidence to support the efficacy of the product at the recommended dose. Since the additive was shown to be safe for piglets, a more sensitive category, the Panel considers that the product is also safe for pigs for fattening.

  The opinion was adopted.[2]

- **Safety and efficacy of Danisco Xylanase G/L (endo-1,4-beta-xylanase) for turkeys for fattening (EFSA-Q-2007-109)**

  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 Danisco Xylanase G/L as a zootechnical additive (functional group: digestibility enhancer) for turkeys for fattening. The safety for the consumer, user, environment and the safety aspects of the genetic modification were considered in a previous opinion of the FEEDAP Panel.[3] Therefore, the current opinion focussed only on the safety and efficacy of the target species proposed.

  This opinion was already discussed during the Plenary meeting of October. At that time, the commenting period for Member States (MS) was still open. After reception and consideration of the comments of the MS, the opinion was presented to the Panel for possible adoption.

  The FEEDAP Panel considers that there is evidence to support efficacy of this product at the minimum recommended dose and also considers the product safe for turkeys for fattening at the recommended use level.

  The opinion was adopted.[4]

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[1] http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_43rd_plenmeet,6.pdf
[2] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej585_biosafsc47_pg_en.pdf
[3] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej548_danisco_xylanase_cff_ly_dff_en,7.pdf
[4] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej586_daniscoxy_tkff_en,1.pdf

5.2. Discussion of the following scientific opinions

- **Safety and efficacy of Avizyme 1505 (endo-1,4-beta-xylanase, alpha-amylase and subtilisin) for turkeys for fattening (EFSA-Q-2007-112)**

  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 Avizyme 1505 as a zootechnical additive (functional group, digestibility enhancer) for turkeys for fattening. This product consists of three enzymes produced by different strains of genetically modified micro-organisms, and has not been authorised in the EC.

  The same product is currently being assessed for the safety for the target species chickens and ducks for fattening, consumer, user, the environment, as well as for the safety aspects of the genetic modification (EFSA-Q-2007-020). At present, the assessment of this application has been stopped since additional data has been asked to the applicant.

  Discussion took place on the efficacy and safety for the target species. Several recommendations were done to the WG to finalise the opinion. The opinion will be presented to the Plenary once again when the safety aspects relating to the genetic modification are addressed in the framework of EFSA-Q-2007-020.

6. PROGRESS REPORT ON ONGOING WORK

The guidance for the assessment of the compatibility of zootechnical microbial additives with antimicrobial substances (EFSA-Q-2007-174) is currently under public consultation. The commenting period will end on 30 November 2007. The Scientific Secretariat updated the Panel on the number and nature of comments received so far.

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 one new application of feed additives seeking authorisation under Regulation (EC) No 1831/2003 since the last Plenary meeting. This application is currently being checked for completeness:

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

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

Applications considered valid for the start of the assessment:

- **Probiotic Lactina® (*Lactobacillus acidophilus, L. helveticus, L. bulgaricus, L. lactis, Streptococcus thermophilus* and *Enterococcus faecium*).** Zootechnical additive for chickens for fattening and pigs (piglets) (EFSA-Q-2006-135).

  The application and the particulars related to this question have been considered valid by EFSA on the 28th October 2007. The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

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

The application and the particulars related to this question have been considered valid by EFSA on the 16 November 2007. The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

- **Advastat (Acarbose).** Zootechnical additive for cattle for fattening and dairy cows. (EFSA-Q-2007-172).

  The application and the particulars related to this question have been considered valid by EFSA on the 30th October 2007. 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 Scientific Coordinator thanked all the Panel members for their participation to the Conference with Stakeholders "**Risk assessment of feed additives in the EU: Present and future**" that took place on 24-25 October in Toulouse. The Conference was organized in five sessions, and allowed the exchange of views through debates and discussion. One session was dedicated to gather Views and expectations of Stakeholders on EFSA's procedures specifically within the remit of the FEEDAP Panel. From this session a series of recommendations were proposed to improve the work of the FEEDAP Unit/Panel and the communication with the applicants and stakeholders. This initiative was welcome by the stakeholders and positive feedback was received from the participants.
- The Scientific Committee and Advisory Forum of EFSA have established a WG on nanotechnologies to address the question on "Risks arising from nanoscience and nanotechnologies on food and feed safety and the environment" EFSA-Q-2007-124. One member of the Panel will participate in this WG.
- The Vice-chair of the Panel reported to the panel the outcome of the Meeting of Chairs of the scientific committees and panels of the EU held in Stockholm on 6-7 November.
- A member of the Panel reported on a meeting held with industry association regarding the preparation of dossiers on flavouring substances.

9. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

The Chair of the Panel informed about the different discussions that took place in the last meeting of the Scientific Committee of EFSA. One of the most relevant issues was the adoption of the opinion on the Qualified Presumption of Safety (QPS) approach for the safety assessment of micro-organisms deliberately added to food and feed.[5]

10. MISCELLANEOUS

Following a request from an applicant, there was a discussion on the data necessary to extend the authorisation of an additive already assessed and authorised for a mammalian pet species to another mammalian pet species. After discussion, the Panel agreed to the following:

- The safety for the user/owner and for the environment from the first application could be extended to the other pet species.
- The safety for the target species should be assessed for each target species. This could be obviated if the additive has demonstrated a comparable and **wide margin of safety in three major species** (including monogastric and ruminant mammals and poultry).

[5] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/sc_op_ej587_qps_en.pdf

- To support efficacy, one dose-titration study would suffice provided that:
  - ✓ efficacy has been demonstrated in the other pet species
  - ✓ The mode of action/effect claimed is the same
  - ✓ The dose range assessed is similar to the dose range authorised for the other pet species.