MINUTES OF THE 43RD PLENARY MEETING

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

(PARMA, 17-18 OCTOBER 2007)

(ADOPTED ON 22 NOVEMBER 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 (1st day), Carlo Stefano Nebbia (2nd day), Walter Rambeck, Atte von Wright (2nd day).

Apologies
Miklós Mézes (2nd day), Carlo Stefano Nebbia (1st day), Guido Rychen, Atte von Wright (1st day), Pieter Wester.

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

European Commission
Mercedes Szekeres (DG SANCO), Giuseppe Simone (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 43rd 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. 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 42ND PLENARY MEETING ON 18-19 SEPTEMBER 2007

The minutes of the 42nd Plenary meeting of the Scientific Panel held on 18-19 September 2007 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **BioPlus® 2B (*Bacillus subtilis and Bacillus licheniformis*) for turkeys for fattening. Compatibility with lasalocid sodium (EFSA-Q-2006-310)**

  The European Commission (EC) requested EFSA to deliver an opinion on the compatibility of the microbial preparation BioPlus® 2B with the coccidiostats lasalocid A sodium in feed for turkeys for fattening. The FEEDAP Panel in a previous opinion[2] could not reach a conclusion on the compatibility between the two products. The applicant has provided new data in the form of an *in vivo* trial.

  The Panel considers that the data provided supports the compatibility of lasalocid with BioPlus® 2B in the form of spore. However, the applicant did not provide conclusive data to support the compatibility of the coccidiostat with the microbial additive in vegetative form. Therefore, the FEEDAP Panel could not conclude on the compatibility of BioPlus® 2B and lasalocid A sodium.

  The opinion was adopted.[3]

- **Safety and efficacy of Carophyll® Stay-Pink (asthaxanthin dimethyldisuccinate) for salmon and trout (EFSA-Q-2007-018)**

  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 asthaxanthin dimethyldisuccinate (Carophyll® Stay-Pink) to be used as a feed additive for salmon and trout (category: sensory additive; functional group: colourants).

  The discussion took place and the Panel considered that there is sufficient evidence to support the efficacy and the safety of the product for animals, consumer/user and the environment. A number of modifications to the register entry were proposed, in particular those limiting the amount of undesirable substances and other potential contaminants of the product.

  The opinion was adopted after some editorial modifications.[4]

- **Compatibility of the microbial product 035, a preparation of *Bacillus subtilis*, with lasalocid sodium, maduramicin ammonium, monensin sodium, narasin, salinomycin sodium and semduramicin sodium in feed for chickens for fattening (EFSA-Q-2007-075)**

[1] http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_42nd_plenmeet_en.pdf
[2] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/1170.html
[3] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej573_bioplus2b_tk_en.pdf
[4] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej574_carophyll_slm_tt_en,3.pdf

The EC has requested EFSA to deliver an opinion on the compatibility of the microbial preparation 035 with six coccidiostats. In a previous opinion,[5] the FEEDAP Panel concluded that the strain tolerated diclazuril, halofuginone and robenidine but was sensitive to maduramicin, monensin, lasalocid sodium and salinomycin. Those data were considered by the FEEDAP Panel to be indicative but *in vivo* studies were considered necessary to reach a conclusion on the compatibility of the strain with commercially used coccidiostats.

The applicant has now provided an *in vivo* trial. The Panel considered that the product in the form of spores is compatible with the six coccidiostats. However, due to the lack of appropriate data on the sensibility of vegetative cells, the Panel was unable to conclude on the compatibility between 035 and the six coccidiostats tested.

The opinion was adopted after some editorial modifications.[6]

- **Guidance for the assessment of the compatibility of zootechnical microbial additives with antimicrobial substances (EFSA-Q-2007-174)**

  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).

  The FEEDAP Panel proposes a stepwise approach to establish compatibility in which an *in vitro* screen is used to exclude those cases where incompatibility is very unlikely, reserving *in vivo* studies for those situations when the *in vitro* results suggest that an incompatibility may exist.

  This document was agreed by the FEEDAP Panel and will be submitted to public consultation. The document and the instructions to submit comments are available on the EFSA website.[7] The deadline to submit comments is 30 November.

- **Safety and efficacy of Avizyme 1505 (endo-1,4-beta-xylanase, alpha-amylase and subtilisin) for chickens and ducks for fattening (EFSA-Q-2007-020)**

  Not discussed due to lack of time.

5.2. Discussion of the following scientific opinions

- **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.[8] Therefore, the current opinion focussed only on the safety and efficacy of the target species proposed.

[5] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620782179.htm
[6] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej575_035_coccid_en.pdf
[7] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178654659278.htm
[8] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej548_danisco_xylanase_cff_ly_dff_en,7.pdf

A first discussion took place. The opinion will be presented to the next Plenary meting, once the commenting period from the Member States is closed.

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

  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 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.

  A first discussion took place and some suggestions for modifications were introduced. The draft opinion will be presented to the next Plenary meeting for discussion and possible adoption.

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:

- **Advastat (Acarbose).** Zootechnical additive for cattle for fattening and dairy cows. (EFSA-Q-2007-172)
- **CreAmino® (Guanidinoacetic acid).** Nutritional additive for chickens for fattening (EFSA-Q-2007-140)

8. NEW REQUESTS RECEIVED FROM EFSA

The FEEDAP Panel has proposed two self-tasks:

- **Functional groups for zootechnical additives as defined under Regulation (EC) No 1831/2003** (EFSA-Q-2007-173). The FEEDAP Panel is requested to review the scientific basis for the different functional groups defined by Regulation (EC) No 1831/2003 under the category zootechnical additives, and propose, if necessary, the creation of new functional groups or categories. The deadline for this self-task is summer 2008.

- **Guidance for the assessment of the compatibility of zootechnical microbial additives with antimicrobial substances** (EFSA-Q-2007-174). The FEEDAP Panel is 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). The deadline for this self-task is end of March 2008.

9. GENERAL INFORMATION FROM EFSA

- Riitta Maijala has been nominated Head of the Department of Risk Assessment, under the Directorate of Science. She joined EFSA on the 1st October.
- The Scientific Coordinator informed the Panel about several meetings that have taken place with industry associations or applicants.

10. MISCELLANEOUS

- Some discussion took place on the decision of the Management Board of EFSA concerning the amended document on the Establishment and operations of the Scientific Committee and Panels (adopted on 11th September 2007)[9] which introduced some modifications on the schema for financial compensation for the panel experts.
- The issue of the revision of the indemnities was raised again by the Panel, who consider that limited progress has been made on this subject. Further action is considered necessary.

[9] http://www.efsa.europa.eu/EFSA/DocumentSet/mb_32ndmeet_annex_a_en_4_1,2.pdf