MINUTES OF THE 52ND PLENARY MEETING

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

(PARMA, 21-22 OCTOBER 2008)

(ADOPTED ON 18 NOVEMBER 2008)

PARTICIPANTS

Panel Members
Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Bogdan Debski (1st day), Jürgen Gropp, Ingrid Halle, Christer Hogstrand, Lubomir Leng, Sven Lindgren, Alberto Mantovani, Miklós Mézes, Carlo Stefano Nebbia, Guido Rychen, Pieter Wester, Atte von Wright.

Apologies
Bogdan Debski (2nd day), Noël Dierick, Anne Katrine Lundebye-Haldorsen, Walter Rambeck.

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

European Commission
Marta Ponghellini, Marina Marini (DG SANCO), Christoph von Holst (DG JRC) (2nd day).

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 52nd Plenary meeting of the FEEDAP Panel. A new member, Prof. Sven Lindgren has joined 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 informed that his institute performed some studies in the dossiers for Avizyme 1505, and therefore he did not take part of the discussions related to these additives.

Paul Brantom declared an interest on Advastat and therefore did not participate in the discussion/adoption of the opinion.

No other interests were declared regarding the items on the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 51ST PLENARY MEETING ON 16-17 SEPTEMBER 2008

The minutes of the 51st Plenary meeting of the Scientific Panel held on 16-17 September 2008 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

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

  The Rapporteur of the working group (WG) presented the question and the draft opinion. This question refers to an application for the authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is asking for authorisation of this product to be used as a zootechnical feed additive in chickens for fattening and ducks. The enzymes contained in this additive are produced by genetically modified micro-organisms, and the safety of the genetic modification is being assessed by the GMO Panel.

  The draft opinion was reviewed and discussion focussed on the efficacy and safety of this additive for the target species. The Panel considered that more information was required in order to complete the assessment. Therefore, the applicant will be requested to provide more information. Once the new information is provided, a modified draft will be prepared by the WG and presented to the Plenary.

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

  The Rapporteur of the WG presented the question and the draft opinion. This question refers to an application for the authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is asking for authorisation of this product to be used as a zootechnical feed additive in turkeys for fattening.

  The panel identified the need for more information to conclude its assessment. Therefore the applicant will be requested to provide more information. Once the new information is provided, a modified draft will be prepared by the WG and presented to the Plenary.

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

  The Rapporteur of the WG presented the question and the draft opinion. This question refers to an application for the authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Advastat® (containing 10 % acarbose produced by *Actinoplanes utahensis* CBS 961.70) to be used as a feed additive for cattle for fattening and dairy cows (category: zootechnical additive; functional group: digestibility enhancer).

  The draft opinion was revised. Based on the data presented, the Panel could not conclude on the efficacy of this product in the target animals because benefits in healthy animals could not be demonstrated. The product is considered to be safe for the target species and for the consumer when used at the proposed levels. The product is considered as potential skin irritant and sensitizer. In the absence of specific data on the major metabolite in excreta, the Panel cannot fully assess the safety of this product for the environment.

[1] http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_51st_plenmeet.pdf?ssbinary=true

The opinion was adopted.[2]

- **Biosaf Sc 47 (*Saccharomyces cerevisiae*) for dairy buffaloes (EFSA-Q-2008-010)**

  The Rapporteur of the WG presented the question and the draft opinion. This question refers to an application for the authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Biosaf Sc47 to be used as a feed additive for dairy buffaloes (category: zootechnical additives; functional group: gut flora stabilisers). This product is currently authorised for several target species and has been evaluated in the past by SCAN and the FEEDAP Panel.

  The draft opinion was reviewed. The Panel considers that the product is efficacious. The active agent is a micro-organism with QPS status and therefore it is considered safe for the target species, the consumer and the environment. No additional hazards to users are expected with this extension of use.

  The opinion was adopted.[3]

- **BioPlus 2B (*Bacillus licheniformis* and *B. subtilis*) for turkeys for fattening – compatibility with lasalocid sodium (EFSA-Q-2008-332)**

  The rapporteur of the WG presented the question and the draft opinion. The Commission asked EFSA to deliver an opinion on the compatibility of BioPlus 2B with the coccidiostat lasalocid sodium when used in feed for turkeys for fattening. In previous opinions,[4,5] the FEEDAP Panel was unable to conclude on the compatibility of the two products due to lack of proper data. The applicant has now provided a new study.

  No signs of incompatibility of both strains composing BioPlus 2B with lasalocid sodium at the authorised level were observed in the new study, which allows concluding to the compatibility of both products.

  The opinion was adopted.[6]

- **035 (*Bacillus subtilis*) for chickens for fattening – compatibility with decoquinate and narasin/nicarbazin (EFSA-Q-2008-423)**

  The rapporteur of the WG presented the question and the draft opinion. This question refers to an application for the authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product 035 o be used as a feed additive for chickens for fattening, containing the coccidiostats decoquinate and narasin/nicarbazin.

  Based on the data provided by the applicant, the FEEDAP Panel considers that 035 is compatible *in vivo* with decoquinate and narasin/nicarbazin when used at the authorised levels.

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[2] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902172778.htm

[3] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902159456.htm

[4] Opinion of the Scientific Panel on additives and products or substances used in animal feed (FEEDAP) on the modification of terms of authorisation of the micro-organism product Bacillus licheniformis (DSM 5749) and Bacillus subtilis (DSM 5750) (BioPlus 2B) authorised as a feed additive in accordance with Council Directive 70/524/EEC. EFSA Journal (2005) 272, 1-8 http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620783809.htm

[5] Compatibility of the microbial preparation of Bacillus licheniformis and Bacillus subtilis (BioPlus 2B) with the coccidiostat lasalocid A sodium in feed for turkeys. EFSA Journal (2007) 573, 1-5 http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178655845332.htm

[6] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902174599.htm

The opinion was adopted.[7]

- **Guidance documents for the assessment of additives for use in animal nutrition in accordance with Regulation (EC) No 1831/2003 (EFSA-Q-2008-408/461)**

  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.

  The following guidance documents were thoroughly discussed and adopted:

  - Technical guidance: Additives already authorised for use in food (EFSA-Q-2008-404).
  - Technical guidance for assessing the safety of feed additives for the environment: (EFSA-Q-2008-408).
  - Technical guidance: Microbial studies (EFSA-Q-2008-461).

  The adopted guidance documents are available on the website.[8]

5.2. Discussion of the following scientific opinions

- **Self-task on functional groups under zootechnical additives (EFSA-Q-2007-173)**

  Not discussed due to lack of time.

6. PROGRESS REPORT ON ONGOING WORK

- The Scientific Co-ordinator (SC) informed the Panel on a meeting that took place with the European Commission regarding the guidance documents adopted by the Panel.
- The SC also informed the Panel on two meetings with industry associations.

7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

The Scientific Committee has launched a public consultation on its "Draft Opinion on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed safety and the Environment". The Panel members were invited to submit their comments.

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 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:

- **Nathuphos (3-phytase).** Zootechnical additive for pigs for fattening (EFSA-Q-2008-692)
- **Formi LHS (potassium diformate).** Zootechnical additive for sows (EFSA-Q2008-693)
- **Soda ash (sodium carbonate).** Technological additive for all species (EFSA-Q-2008-694)
- **AviPlus (citric acid, sorbic acid and thymol).** Zootechnical additive for weaned piglets (EFSA-Q-2008-701)

[7] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902174767.htm
[8] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_feedap_technical_guidance.htm

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

Applications considered valid for the start of the assessment:

- **Roxazyme G2 (endo-1,4-beta-glucanase, endo-1,(3)4-beta-glucanase and endo-1,4-beta-xylanase).** Zootechnical additive for poultry, and for chickens and turkeys for fattening, laying hens, ducks, and piglets (weaned) (EFSA-Q-2007-185) Validated on 2 October 2008
- **Selenium enriched yeast (*Saccharomyces cerevisiae*).** Nutritional additive for all species (EFSA-Q-2008-381) Validated on 18 September 2008
- **Natugrain Wheat TS (Endo-1,4-ß-xylanase).** Zootechnical additive for chickens for fattening and ducks. (EFSA-Q-2008-418). Validated on 10 October 2008

8.3. New applications under Regulation (EC) No 1829/2003

- **Application for authorisation of genetically modified PL73 Escherichia coli (LM) for feed use (dried killed bacterial biomass) (EFSA-GMO-FR-2008-61)** (EFSA-Q-2008-669)

9. GENERAL INFORMATION FROM EFSA

A member of the Finance unit made a short presentation on the financial statement application.

10. MISCELLANEOUS

- Assessment of tolerance studies

  A discussion took place on the evaluation of tolerance studies in the framework of the assessment of the safety for target animals of feed additives. The FEEDAP Panel has decided not to accept tolerance studies that are not conducted and reported according to the currently applicable guidelines.

- The issue of formulation-dependant properties of non-holder specific additives was discussed, particularly in relation to user safety, stability and homogeneity of mixing. It was decided that these issues should be further explored.