MINUTES OF THE 53RD PLENARY MEETING

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

(PARMA, 18-19 NOVEMBER 2008)

(ADOPTED ON 9 DECEMBER 2008)

PARTICIPANTS

Panel Members
Georges Bories, Paul Brantom, Andrew Chesson, Pier Sandro Cocconcelli, Bogdan Debski, Noël Dierick, Jürgen Gropp, Ingrid Halle (1st day), Christer Hogstrand, Lubomir Leng, Anne Katrine Lundebye-Haldorsen, Alberto Mantovani, Miklós Mézes, Carlo Stefano Nebbia (2nd day), Walter Rambeck, Guido Rychen (1st day), Pieter Wester, Atte von Wright.

Apologies
Joaquim Brufau de Barberà, Joop de Knecht, Ingrid Halle (2nd day), Sven Lindgren, Carlo Stefano Nebbia (1st day), Guido Rychen (2nd day).

EFSA
Jaume Galobart, Rosella Brozzi (scientific staff), Nicola Reynolds (administrative staff).

European Commission
Marta Ponghellini, Marina Marini (DG SANCO).

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 53rd 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

No interests were declared regarding the items on the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 52ND PLENARY MEETING ON 21-22 OCTOBER 2008

The minutes of the 52nd Plenary meeting of the Scientific Panel held on 21-22 October 2008 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Vitamin A (EFSA-Q-2006-121)**

  The Rapporteur of the working group (WG) presented the question and the draft opinion. EFSA was requested to deliver an opinion on the risks of high levels of vitamin A for the consumer resulting from the intake of products of animal origin. EFSA was also asked to estimate the dietary contribution of vitamin A for European consumers from the various different sources. Should the overall intake exceed the Upper Level, EFSA should comment on the benefit of decreasing the maximum permitted levels of addition for vitamin A as a nutritional additive under Regulation (EC) No 1831/2003. In addition, EFSA opinion should also advice on the potential zootechnical implications of lowering the levels of vitamin A intake by food producing animals, taking into account all possible sources of vitamin A (added as nutritional additive but also in the form of precursors, natural presence in feedingstuffs, etc…). In the respect the safety for the animals should be assessed and also the environmental impact as is mandatory for the evaluation of all feed additives.

  The opinion was reviewed. The Panel concluded the following:

  – the current UL (3000 µg RE from preformed vitamin A day^{-1}), established by the SCF is considered still appropriate taking into account the available data;
  – a maximum intake of 1500 µg RE day^{-1} can be considered as a Guidance Level (GL) for persons at a greater risk of osteoporosis and bone fracture (particularly post-menopausal women);
  – the main exposure to preformed vitamin A comes from consumption of liver and milk, including all dairy products;
  – the mean intake of preformed vitamin A in the adult population in Europe is estimated between 400 and 1200 µg RE day^{-1} in men and between 350 and 1000 µg RE day^{-1} in women;
  – the risk of exceeding the UL (and GL) for preformed vitamin A is predominantly related to liver consumption, but also from the consumption of supplements containing vitamin A.

  The Panel issued recommendations for maximum contents of vitamin A in feed for most of the animal species as a precautionary measure for the protection of consumers. Insufficient data were available for fish and some minor species.

  The Panel thanked Prof. Andrew Renwick and Davide Arcella for their valuable contribution to this opinion.

  The opinion was adopted.

- **Ronozyme NP (6-Phytase) for chickens for fattening (EFSA-Q-2007-133)**

[1] http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_52nd_plenmeet.pdf?ssbinary=true

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 chickens for fattening. This enzyme preparation is produced by a genetically modified micro-organism. The GMO Panel assessed the safety of the genetic modification and adopted their part of the opinion on 29 October 2008.

The draft opinion was previously discussed in the plenary meetings of December 2007 and May 2008. The Panel considers that the product is safe for the target species and is efficacious. No concerns are expressed for the safety for the consumer and the environment. The product is considered a respiratory sensitiser.

The opinion was adopted.[2]

- **Bactocell PA 10 (*Pediococcus acidilactici*) for fish (EFSA-Q-2007-205)**

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 Bactocell PA 10 to be used as a feed additive for fish (category: zootechnical additive; functional group: other zootechnical additives).

The draft opinion was discussed and the Panel identified the need for further information.

- **L-valine for all species (EFSA-Q-2008-413)**

The rapporteur of the WG presented the question and the draft opinion. In a previous opinion,[3] EFSA concluded that there was not enough information to conclude on the safety of L-valine with a minimum specification of 95% purity. The applicant has provided new data. The Commission asked EFSA to review the data provided by the applicant and deliver a new opinion on the safety of L-valine for all species.

The draft opinion was reviewed. The Panel concluded that there are no safety concerns resulting from the use of the additive L-valine in all animal species with a minimum content in the dry matter of 98 % L-valine and unidentified impurities of less than 1 %.

The opinion was adopted.[4]

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

Not discussed due to lack of time.

5.2. Discussion of the following scientific opinions

- **Availa® Cr (chromium methionine) for all species (EFSA-Q-2006-066)**

Not discussed due to lack of time.

6. PROGRESS REPORT ON ONGOING WORK

- A member of the Panel summarised the discussion held with an industry association, during a meeting held in September, related with the preparation and presentation of dossiers.

[2] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902199809.htm
[3] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178712206517.htm
[4] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902207009.htm

7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

Not discussed.

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 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:

- **Finase EC (6-phytase).** Zootechnical additive for chickens for fattening/chickens for laying, laying hens, turkeys for fattening/turkeys for breeding, piglets (weaned), pigs for fattening, sows, ducks and other minor poultry species (i.e., geese, quail, pigeon, pheasants and other game birds) (EFSA-Q-2008-748)
- **Clinacox® 0.5% (diclazuril).** Coccidiostat for chickens for fattening (EFSA-Q2008-749)
- **Cygro 10G (maduramicin).** Coccidiostat for chickens for fattening (EFSA-Q-2008-750)
- **Avatec (lasalocid sodium A).** Coccidiostat for turkeys (EFSA-Q-2008-751)
- **Cycostat 66G (robenidine hydrochloride).** Coccidiostat for rabbits for breeding and fattening purposes (EFSA-Q-2008-752)
- **Cygro® 10G (maduramicin ammonium).** Coccidiostat for turkeys (EFSA-Q-2008-757)

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

Applications considered valid for the start of the assessment:

- **Finase L and P (3-phytase).** Zootechnical additive for laying hens, turkeys for fattening, ducks for fattening, pheasants and other game birds and sows. (EFSA-Q-2008-378) Validated on 23 October 2008.
- **Cylactin®/Cernivet® (*Enterococcus faecium*).** Zootechnical additive for chickens for fattening (EFSA-Q-2008-422) Validated on 27 October 2008.
- **Ronozyme ProAct (serine protease).** Zootechnical additive for chickens for fattening. (EFSA-Q-2008-431). Validated on 27 October 2008.
- **Maxiban 160G (narasin/nicarbazin).** Coccidiostat for chickens for fattening (EFSA-Q-2008-474). Validated on 12 November 2008.

9. GENERAL INFORMATION FROM EFSA

- The Panel was informed that the public call for expressions of interest for membership of the Scientific Panels of EFSA is now open. The deadline for applications is 7 January 2009. They were also invited to fill in the Expert Survey.

10. MISCELLANEOUS

- The panel was informed about two public consultations from the EC:
    - "Effects of the Active Substances in Biocidal Products on Antibiotic Resistance". Open until 30 November.
    - "Risk assessment methodologies and approaches for mutagenic and carcinogenic substances." Open until 2 December.
- The panel was also informed that the Standing Committee of the Food Chain and Animal Health has agreed on using the EFSA's proposal list on prioritisation for the re-evaluation of feed additives.