MINUTES OF THE 56TH PLENARY MEETING

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

(PARMA, 3-5 MARCH 2009)

(ADOPTED ON 1 APRIL 2009)

PARTICIPANTS

Panel Members

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

Apologies

Pier Sandro Cocconcelli (3rd day), Christer Hogstrand (3rd day), Anne Katrine Lundebye-Haldorsen (3rd day), Alberto Mantovani (1st day), Carlo Stefano Nebbia (3rd day), Guido Rychen (3rd day).

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Rosella Brozzi, Lucilla Gregoretti, Matteo Innocenti, Montserrat Anguita (scientific staff), Nicola Reynolds (administrative staff).

European Commission

Marta Ponghellini, Willem Penning (2nd day), 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 56th 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

EFSA secretariat screened the annual declaration of interest (ADoI) and specific declaration of interest (SDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests. For further details on the outcome of the screening please refer to Annex I.

4. ADOPTION OF THE DRAFT MINUTES OF THE 55TH PLENARY MEETING ON 3-5 FEBRUARY 2009

The minutes of the 55th Plenary meeting of the Scientific Panel held on 3-5 February 2009 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **ColiCure (*Escherichia coli*) for horses (EFSA-Q-2005-167)**

  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 the authorisation of this product as a zootechnical additive for horses.

  The draft opinion was reviewed. The Panel considered that the experiments provided establish the potential of ColiCure to reduce the risk of gastrointestinal disturbances in horses. The product is considered safe for the target species, consumers, users and the environment.

  The opinion was adopted.[2]

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

  Not discussed due to lack of time

- **CreAmino™ (Guanidinoacetic acid) for chickens for fattening (EFSA-Q-2007-050)**

  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 the authorisation of this product as a nutritional additive for chickens for fattening.

  The draft was reviewed. The Panel concluded that guanidinoacetic acid (GAA) at the lowest recommended dose (600 mg kg^{-1} feed) improves performance of chickens for fattening, however the effects are most consistently seen at 800 mg GAA kg^{-1} feed. The Panel considered this dose safe, but it was not possible to conclude on the safety of the highest recommended dose (1200 mg kg^{-1} feed) due to lack of data. No concerns were identified for consumer, user or environmental safety.

  The opinion was adopted.[3]

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

  Not discussed due to lack of time

- **Yea-Sacc 1026® (*Saccharomyces cerevisiae*) for horses (EFSA-Q-2008-009)**

  The Rapporteur of the WG presented the question and the draft opinion. This question refers to an application for the re-evaluation of a feed additive (Article 10.2) and for the authorisation of a new use of the feed additive (Article 4(1)) under Regulation (EC) No 1831/2003. This product was already authorised for use in horses from two months post-weaning onwards. The applicant is asking for the re-evaluation of this additive for horses

[1] http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_55th_plenmeet_en.pdf?ssbinary=true
[2] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902391773.htm
[3] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902403006.htm

from two months post-weaning onwards and for its authorisation to be used as a zootechnical additive in horses of all ages, and for a lower inclusion level in feed.

The draft opinion was reviewed. The applicant has provided evidence of efficacy of the product at the dose for which it was previously authorised. However, no evidence has been provided to support a lower dose. The active agent, *Saccharomyces cerevisiae*, is considered by EFSA to qualify for QPS status, and therefore it is considered safe for the target species, the consumer and the environment. The safety for the user of the product was established already in a previous assessment by the FEEDAP Panel.[4]

The opinion was adopted.[5]

- **Bonvital (*Enterococcus faecium*) for chickens for fattening (EFSA-Q-2008-289)**

  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 additive in chickens for fattening.

  The draft opinion was reviewed. The Panel considered that the data provided in the dossier is not sufficient to support the efficacy of the product. The FEEDAP Panel was unable to conclude on the safety of Bonvital for chickens for fattening in the absence of studies meeting the relevant requirements. The additive is considered safe for the consumer, user and the environment.

  The opinion was adopted.[6]

- **Selfsaf (selenium enriched yeast) for all species (EFSA-Q-2008-381)**

  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 nutritional additive for all species.

  The draft opinion was reviewed. The studies provided showed that Selsaf is a source of bioavailable Se for all animal species. The product is considered safe for the target species and the consumers when supplemented up to the maximum authorised content of Se in complete feed. Selsaf is not an eye or skin irritant but its potential for skin or respiratory sensitisation cannot be excluded. The product is considered safe for the environment.

  The opinion was adopted.[7]

- **Bactocell PA 10 (*Pediococcus acidilactici*) for shrimps (EFSA-Q-2008-421)**

  Not discussed due to lack of time.

- **Levucell SC 20 (*Saccharomyces cerevisiae*) for leisure horses (EFSA-Q-2008-472)**

  Not discussed due to lack of time.

[4] http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/opinion_amended_feedap_031.pdf?ssbinary=true
[5] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902390754.htm
[6] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902338514.htm
[7] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902338514.htm

6. PROGRESS REPORT ON ONGOING WORK

Not discussed.

7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

Not discussed.

8. NEW REQUESTS TO EFSA RECEIVED FROM THE EUROPEAN COMMISSION

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

Applications considered valid for the start of the assessment:

- **Natuphos (3-phytase).** Zootechnical additive for pigs for fattening (EFSA-Q-2008-692) Validated on 25 February 2009.
- **Formi™ LHS (potassium diformate).** Zootechnical additive for sows (EFSA-Q-2008-693) Validated on 13 February 2009.
- **Koffogran (nicarbazin).** Coccidiostat for chickens for fattening (EFSA-Q-2009-00225) Validated on 13 February 2009.

9. GENERAL INFORMATION FROM EFSA

- A call for proposals under Article 36 has been launched by the FEEDAP unit on mycotoxin detoxifying agents. The objective of this call if to produce a review document on the different mycotoxin detoxifying agents, its mode of action and possible consequences in food/feed safety.

10. MISCELLANEOUS

- Dr. Willem Penning, Head of Unit on Animal Feed at DG SANCO, attended the morning session of the second day of the Plenary meeting. He gave some feedback on some recent opinions adopted by the Panel.
- The Panel agreed on comments to be sent to the BIOHAZ Panel regarding the public consultation on the draft opinion on the use and mode of action of bacteriophages in food production.

Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOI OR SDOIs

a) CONFLICT LEVEL B: In the ADoI or in the SDoI filled for the present meeting Dr Joaquim Brufau declared that his institute had performed some studies for the dossiers on Selsaf and CreAmino™. In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest (level B). Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest, the said expert incurs in the limitations identified under point C.III.b[8] that is, he cannot actively participate in the final discussion. However, he can be present to answer questions addressed specifically to him.

b) INTERESTS BUT NO CONFLICT: In the ADoI or in the SDoI filled for the present meeting Dr Walter Rambeck declared that he had been involved in some trials for the dossiers on CreAmino™ and Bonvital for different target species than those in the present dossiers. In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a conflict of Interest for the expert concerned.

INTERESTS AND ACTIONS RESULTING FROM DECLARATIONS DONE AT THE MEETING

c) NO FURTHER INTERESTS: With regard to this meeting no other interests than those already declared in the ADoI or in a previous SDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof were declared by the experts.

[8] Implementing act to the policy on declaration of interests procedure for identifying and handling potential conflicts of interest.
http://www.efsa.europa.eu/cs/BlobServer/General/mb_annex_procedure_doi_en%20221008,0.pdf?ssbinary=true