MINUTES OF THE 34TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 17-19 OCTOBER 2006)

(ADOPTED ON 21 NOVEMBER 2006)

PARTICIPANTS

Panel Members:
Georges Bories, Paul Brantom, Joaquim Brufau de Barberà (1st - 2nd day), Andrew Chesson, Pier Sandro Cocconcelli (1st - 2nd day), Bogdan Debski, Anders Franklin, Jürgen Gropp, Ingrid Halle, Christer Hogstrand, Joop de Knecht, Lubomir Leng, Anne Katrine Lundebye-Haldorsen, Miklós Mézes (1st - 2nd day), Carlo Stefano Nebbia (2nd - 3rd day), Walter Rambeck, Guido Rychen (1st - 2nd day), Atte von Wright, Pieter Wester (1st - 2nd day)

Apologies
Joaquim Brufau de Barberà (3rd day), Pier Sandro Cocconcelli (3rd day), Noël Dierick, Alberto Mantovani, Miklós Mézes (3rd day), Carlo Stefano Nebbia (1st day), Guido Rychen (3rd day), Pieter Wester (3rd day).

EFSA
Claudia Roncancio-Peña, Jaume Galobart, Lucilla Gregoretti, Maria Vittoria Vettori (scientific staff), Ketty Antonelli (administrative staff)

European Commission
Täina Sateri (video conference), Marta Ponghellini (DG Health and Consumer Protection); 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 34rd Plenary meeting of the FEEDAP Panel, and introduced Prof. Bogdan Debski, as a new member of the Panel.

Members not able to attend the meeting had sent their apologies (see under participants).

2. INTRODUCTION BY EFSA EXECUTIVE DIRECTOR

Mrs. Catherine Geslain-Lanéelle introduced herself and explained the main priorities of EFSA in the coming years. It was highlighted the need to further develop scientific cooperation and networking. She thanked the Panel for the work that has been undertaken. Dr. Herman B.W.M. Koëter, Deputy Executive Director and Director of Science informed the panel on the next Colloquium on "Cumulative risk assessment of pesticides to human health: the way forward" that will be held in Parma on 28-29 November 2006.

3. ADOPTION OF THE AGENDA

The agenda was adopted.

4. DECLARATIONS OF INTEREST

Joaquim Brufau informed that his institute has participated in some of the studies for the product Safizym X, and therefore withdraw himself of the discussion on this product. No other interests were declared relevant to the items of the agenda.

5. ADOPTION OF THE DRAFT MINUTES OF THE 33RD PLENARY MEETING ON 12-13 SEPTEMBER 2006

The minutes of the 33rd plenary meeting of the Scientific Panel held on 12-13 September 2006 were reviewed and adopted.

6. WORK PROGRAM

6.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of Phyzyme XP 5000L/5000G (6-phytase) for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening, piglets (weaned), pigs for fattening and sows (EFSA-Q-2005-080)**

  The Rapporteur of the WG on Enzymes introduced the draft opinion. This question refers to a feed additive application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Phyzyme XP 5000L and 5000G to be used as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening, piglets (weaned), pigs for fattening and sows (category: zootechnical additives; functional group: digestibility enhancers and substances which favourably affect the environment).

  The draft was reviewed in detail. The applicant has provided evidence of efficacy for all target species, but not at the lowest recommended dose for some of them. Safety for the target species has been demonstrated at the maximum recommended dose. The safety for the consumer, user and environment were already assessed by EFSA in a previous opinion on Phyzyme XP (The EFSA Journal (2006) 350)[1].

  The opinion was adopted subject to some editorial modifications.

- **Safety and efficacy of 035 (*Bacillus subtilis*) for chickens for fattening (EFSA-Q-2005-237)**

  The Rapporteur of the WG on Micro-organisms introduced the draft opinion. This question refers to a feed additive application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product 035 to be used as a feed additive for chickens for fattening (category: zootechnical additives; functional group: gut flora stabilisers).

[1] Opinion of the Scientific Panel on Additives and Products of Substances used in Animal Feed and the Scientific Panel on Genetically Modified Organisms on the safety and efficacy of the enzymatic preparation Phyzyme XP (6-Phytase) for use as feed additive for chickens. The EFSA Journal (2006) 350, 1-14.
http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/1468.html

The draft opinion was reviewed. The efficacy of the additive has been demonstrated at the minimum recommended dose. The Panel also concluded that the safety for the target species has been demonstrated with a margin of safety of at least 100. The product is also considered safe for the consumers, users and the environment.

The opinion was adopted.

- **Safety and efficacy of Safizym X (endo-1,4-beta-xylanase) for piglets (EFSA-Q-2005-276)**

  The Rapporteur of the WG on Enzymes introduced the draft opinion. This question refers to a feed additive application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Safizym X to be used as a feed additive for piglets (category: zootechnical additives; functional group: other zootechnical additives).

  The draft was discussed. The applicant has provided enough evidence to support the safety for the target species. However, efficacy has been demonstrated at the recommended level (1680 IFP/kg) but not enough data has been provided to support the minimum content claimed (840 IFP/kg). The FEEDAP Panel considers that the functional group should be changed to digestibility enhancer.

  The opinion was adopted with minor editorial modifications.

- **L-Histidine Monohydrochloride Monohydrate for salmonids (EFSA-Q-2006-079)**

  The Rapporteur of the WG introduced the question and the draft opinion. EFSA already evaluated this product under Directive 82/471/EEC. This application has now been submitted under Regulation (EC) No 1831/2003, and therefore EFSA has been requested to verify the Community Reference Laboratory (CRL) report on the method of analysis for the determination of the feed additive, as well as on the post-market monitoring of the product L-histidine monohydrochloride monohydrate as feed additive for use in salmonids.

  The CRL reports that a fully validated method for the determination of histidine in the feed additive and in the feedingstuffs is available. Further testing or validation is not considered necessary.

  Regarding the post market monitoring the applicant will follow the requirements of the Feed Hygiene Regulation.

  The opinion was adopted subject to some editorial modifications.

- **Safety and efficacy of Clinacox 0.5% (Diclazuril) for rabbits for fattening and breeding (EFSA-Q-2004-147)**

  EFSA has been requested to deliver an opinion on the safety and efficacy of the product Clinacox 0.5% for the target species rabbits for fattening and breeding. The Rapporteur of the WG introduced the draft opinion and the developments regarding the new submission of data.

  The discussion focused on the metabolism, residues and safety for the consumer sections. The diclazuril derived compound R070016 has been identified as a significant metabolite in rabbit fat. Moreover, the metabolic studies performed in the rats and the *in vitro* studies carried out in the rat and rabbit hepatocytes failed to identify this metabolite. As a consequence, no assurance exists that the potential toxicity of the compound R070016 has been evaluated through an appropriate set of toxicological studies, in particular regarding genotoxicity. The applicant supplied a Deductive Estimation of Risk from Existing

Knowledge (DEREK) analysis and concluded that no additional study appeared to be necessary.

After intensive discussion, the FEEDAP Panel considered that the DEREK approach is still a matter of research and has not been validated yet as an appropriate surrogate to the standard battery of toxicological tests. Consequently the Panel concluded that further information will be requested to the applicant.

- **Safety and efficacy of Kofa®Grain pH5 (sodium benzoate, propionic acid, sodium propionate) for cattle for fattening (EFSA-Q-2006-032)**

The Rapporteur of the WG introduced the question and the draft opinion. The Commission requested EFSA to issue an opinion on the safety and efficacy of Kofa®Grain as preservative in feed for cattle for fattening. This product was already assessed by SCAN, and is currently authorised for use in pigs and dairy cows. The applicant has now provided data to support efficacy and safety for cattle for fattening.

The applicant has provided enough evidence to support the safety of Kofa®Grain for the target species. However, efficacy of the product in preventing fungal growth in maize kernels could not be demonstrated at the lowest inclusion rate proposed.

The FEEDAP Panel concluded that there is no concern on the safety for the consumer and the environment. Regarding the user safety, appropriate safety measures should be taken.

The opinion was adopted with some editorial modifications.

6.2. Discussion of the following scientific opinions

- **Safety and efficacy of Selenium enriched yeast (*Saccharomyces cerevisiae*) for all species (EFSA-Q-2005-117)**

A member of the WG introduced the draft opinion and informed the plenary on the background and the terms of reference of this question; which refers to a joint application under Article 4(1) of Regulation (EC) No 1831/2003. The applicants are seeking authorisation of the product Selenium enriched yeast (*Saccharomyces cerevisiae*) to be used as a feed additive for all species (category: nutritional additives; functional group: compounds of trace elements).

The discussion focused on the introduction and the efficacy sections where major changes were introduced. The document will be modified accordingly and presented in the next plenary meeting in November for possible adoption.

7. PROGRESS REPORT ON ONGOING WORK

- **Use of functional groups under zootechnical additives**

Since the entry into force of Regulation (EC) No 1831/2003, it has become apparent that applicants have some problems in understanding the functional group “gut flora stabilisers” of the category “zootechnical additives”. In practice that means that a lot of additives are assigned to the “other zootechnical additives” functional group, without justification. Therefore, the WG on Micro-organisms prepared a discussion paper reviewing the scientific basis for the different functional groups under this category. There was a discussion on the final scope of the document, and it was agreed that in a first step a deeper analysis of the scientific basis for the current functional groups and categories for feed additives will be conducted.

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:

- **Probiotic Lactina (*Lactobacillus acidophilus, L. helveticus, L. bulgaricus, L. lactis, Streptococcus thermophilus* and *Enterococcus faecium*).** Zootechnical additive for chickens for fattening and piglets **(EFSA-Q-2006-135).**
- **BioPlus 2B (*Bacillus licheniformis* and *B. subtilis*).** Zootechnical additive for sows **(EFSA-Q-2006-136)**
- **Danisco Xylanase (endo 1,4 ß-xylanase).** Zootechnical additive for chickens for fattening, laying hens and ducks for fattening **(EFSA-Q-2006-137).**
- **Clinacox 0.5% (diclazuril).** Coccidiostat for chickens for fattening, turkeys for fattening and chickens reared for laying **(EFSA-Q-2006-139)**

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

Applications considered valid for the start of the assessment:

- **Naturose® Natural Astaxanthin. Sensory additive for salmon and trout (EFSA-Q-2005-225)**

  The application and the particulars related to the question on Naturose have been considered valid by EFSA on the 4th October 2006.

  The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

- **Bonvital (*Enterococcus faecium*). Zootechnical additive for piglets, pigs for fattening and dogs (EFSA-Q-2006-061)**

  The application and the particulars related to the question on Bonvital have been considered valid by EFSA on the 3rd October 2006.

  The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

- **Biosaf Sc 47 (Saccharomyces cerevisiae NCYC Sc47). Zootechnical additive for calves for rearing (EFSA-Q-2006-067).**

  The application and the particulars related to the question on Biosaf Sc 47 have been considered valid by EFSA on the 12th October 2006.

  The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

8.3. New questions under Regulation (EC) No 178/2002

- **Setting a common MRL for Elancoban® and Coxidin® (monensin sodium) (EFSA-Q-2006-167)**

  An urgent request from the European Commission has been sent to EFSA, to take the necessary steps to suggest a single MRL for the coccidiostats Elancoban® and Coxidin® (monensin sodium).

  A WG has been established and the first meeting will take place on 19th and 20th October. The draft opinion will be presented in the next plenary meeting in November, for possible adoption.

9. GENERAL INFORMATION FROM EFSA

- Mrs. Claudia Roncancio Peña, until now deputy head of the FEEDAP team has been appointed officially Head of Unit and Scientific Co-ordinator (SC) of the FEEDAP Panel.
- A WG of the Standing Committee on Animal Health and Food Chain took place on 9th October to deal with the new guidelines for the assessment of feed additives. The Secretariat attended to this meeting and reported back to the Panel.
- A meeting took place with the European Commission, to have a common understanding on the general issues and the time frame related with the development of the Guidelines for the Applications under Regulation (EC) No 1831/2003 on Flavouring Additives. EFSA established a WG which will work on the development of these guidelines.
- The Secretariat and some Panel members reported to the Panel on several meetings with industry associations or applicants.

10. MISCELLANEOUS

None