MINUTES OF THE 39TH PLENARY MEETING

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

(PARMA, 17-19 APRIL 2007)

(ADOPTED ON 12 JUNE 2007)

PARTICIPANTS

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

Apologies
Anders Franklin (3rd day), Alberto Mantovani, Carlo Stefano Nebbia (3rd day), Guido Rychen (3rd day).

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

European Commission
Christoph von Holst (1st and 2nd day) (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 39th 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 after the inclusion of the item regarding the working document on extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition.

3. DECLARATIONS OF INTEREST

Joaquim Brufau informed that his institute participated in a trial for Rovabio™ PHY AP/LC. No other interests were declared relevant to the items of the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 38TH PLENARY MEETING ON 7-8 MARCH 2007

The minutes of the 38th plenary meeting of the Scientific Panel held on 7-8 March 2007 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of L-Arginine for all animal species (EFSA-Q-2005-043)**

  The Rapporteur of the Working Group (WG) introduced the question and 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 an authorisation of the product L-arginine produced by fermentation of an isolated strain of *Corynebacterium glutamicum* (ATCC-13870) as a nutritional additive under the functional group 'Amino acids, their salts and analogues' for all species.

  The FEEDAP Panel considers that recognized nutrients do not need demonstration of efficacy in long term studies, instead bioavailability studies may be used to demonstrate the extent to which a novel form/source of a nutrient can substitute for an equivalent already established nutrient. The product L-arginine has shown to be bio-available. The safety studies provided demonstrate that L-arginine is safe for the target species, the consumer of food of animal origin and the environment. The use of personal protective measures is recommended for the users of this product,

  The opinion was adopted after some editorial changes.[2]

- **Safety and efficacy of Rovabio™ PHY AP/LC (3-phytase) for chickens for fattening, laying hens, piglets and pigs for fattening (EFSA-Q-2005-281)**

  The Rapporteur of the WG introduced the question and 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 Rovabio™ PHY AP/LC, which is a preparation of 3-phytase produced by the genetically modified micro-organism *Penicillium funiculosum* to be used as a zootechnical feed additive (functional group: digestibility enhancers) for chickens for fattening, laying hens, piglets and pigs for fattening. The GMO Panel assessed the safety of the genetic modification and adopted their part of the opinion on 22 March 2007.

  The product has a limited stability when added to premixtures and feedingstuffs. Evidence of efficacy has been provided for all target species. The product is considered to be safe for the target species, the consumer of food products from animals fed with the additive, the user and the environment.

  The opinion was adopted after some editorial changes.[3]

- **Safety and efficacy of Natugrain® Wheat TS (endo-1,4-beta-xylanase) for turkeys for fattening (EFSA-Q-2006-119)**

[1] http://www.efsa.europa.eu/en/science/feedap/feedap_meetings/feedap_38th_meeting.html
[2] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej473_L-arginine.html
[3] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej471_rovabio.html

The Rapporteur of the WG introduced the question and 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 Natugrain® Wheat TS to be used as a zootechnical feed additive (functional group: digestibility enhancers) in turkeys for fattening. This product is provisionally authorised for its use in chickens for fattening and the FEEDAP Panel delivered an assessment on the safety for the target species, consumer, user and the environment.

The studies presented by the applicant support the efficacy of the product at a dose of 560 TXU kg^{-1} complete feed. The lowest dose proposed by the applicant (400 TXU kg^{-1}) was not tested. The safety for the target species has been demonstrated in two tolerance trials.

The opinion was adopted.[4]

- **Safety of Natuphos® (3-phytase) for laying hens and turkeys for fattening (EFSA-Q-2007-049)**

The Rapporteur of the WG introduced the question and the draft opinion. In a previous opinion on this product,[5] the FEEDAP Panel was not able to conclude on the safety of this enzymatic preparation for laying hens and turkeys for fattening. The applicant has provided new tolerance studies.

Based on this information, the FEEDAP Panel concludes that Natuphos® is safe for laying hens and turkeys for fattening under the conditions of use proposed.

The opinion was adopted.[6]

- **Safety of Kemzyme® W Dry (endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, alpha-amylase, bacillolysin and endo-1,4-beta-xylanase) for laying hens (EFSA-Q-2007-073)**

The Rapporteur of the WG introduced the question and the draft opinion. In a previous opinion on this product,[7] the FEEDAP Panel was not able to conclude on the safety of this enzymatic preparation for laying hens. The applicant has provided a new tolerance study. Based on this new study, the FEEDAP Panel concludes that Kemzyme® W Dry is safe for laying hens.

The opinion was adopted.[8]

5.2. Discussion of the following scientific opinions

- **Safety and efficacy of Safizym X (endo-1,4-beta-xylanase) for ducks (EFSA-Q-2006-320)**

The Rapporteur of the WG introduced the question and 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 zootechnical feed additive (functional group: other zootechnical additives) in ducks. This product is already authorised for chickens for fattening, turkeys for fattening and laying hens.

[4] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej473_L-arginine.html
[5] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/1568.html
[6] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej472_natuphos_ly_tk.html
[7] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/1172.html
[8] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej475_kemzyme_w_dry_ly.html

A first discussion on the draft opinion took place. The opinion will be reviewed once the Community Reference Laboratory (CRL) has delivered its assessment report on the methods of analysis for possible adoption.

- **Safety and efficacy of Calsporin® (*Bacillus subtilis*) for chickens for fattening (EFSA-Q-2007-040)**

  The Rapporteur of the WG introduced the question and the draft opinion. This question refers to the modification of an existing authorisation of a feed additive under Article 13(3) of Regulation (EC) No 1831/2003. The applicant is seeking to reduce the minimum dose from 1×10^9 cfu kg^{-1} complete feedingstuff to 0.5×10^9 cfu kg^{-1}.

  Some discussion took place. This draft opinion will be reviewed again once the CRL has delivered its assessment report on the methods of analysis for possible adoption.

- **Safety and efficacy of Natuphos® (3-phytase) for ducks for fattening (EFSA-Q-2007-041)**

  The Rapporteur of the WG introduced the question and the draft opinion. This question refers to a feed additive application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is asking for an extension of use of the product Natuphos®, which is a preparation of 3-phytase, as a zootechnical additive (functional group: digestibility enhancer) for ducks.

  A first discussion on the draft took place. Once the CRL report is available, the opinion will be reviewed again for possible adoption.

- **Safety and efficacy of Ronozyme P/Bio-Feed Phytase (6-phytase) for ducks for fattening (EFSA-Q-2006-060)**

  Not discussed due to lack of time.

6. PROGRESS REPORT ON ONGOING WORK

- **Draft Guidance on the assessment of compatibility of microbial additives with anti-microbial substances**

  A number of applications have been submitted requesting the assessment of the compatibility of microbial feed additives with substances that possess an antimicrobial activity (mainly coccidiostats and organic acids). The FEEDAP Panel has established a self-tasking activity in order to draft a guidance document that will help the applicants when preparing dossiers related with the compatibility of microbial additives with anti-microbial substances.

  A first discussion regarding the minimum requirements took place. The WG on micro-organisms will now continue the work to draft a guidance document that will be presented to the Panel when ready.

- **Extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition**

  EFSA was consulted by the European Commission on the development of guidelines for the assessment of additives for use in animal nutrition, within the framework of Article 7 of Regulation (EC) No 1831/2003. In May 2006, EFSA delivered its proposal on "Guidelines/guidance" to the European Commission. In this proposal, specific provisions were considered to allow the extrapolation of data from studies performed in major species to minor species.

A number of applications have been received for additives to be used in minor species. In order to help the applicants in the preparation of dossiers for additives for minor species, the FEEDAP Panel has prepared a working document detailing its views on how the extrapolation of efficacy and safety from major to minor species could be done in practice. This working document provide further details from that one already sent to the European Commission and will be updated when the adoption of the guidelines for the assessment of feed additives.

This working document can be found in the EFSA's website.[9]

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 one new application of feed additives seeking authorisation under Regulation (EC) No 1831/2003 since the last plenary meeting. This application is currently being checked for completeness:

- **Coxidin® 25% (Monensin sodium).** Coccidiostat for turkeys for fattening **(EFSA-Q-2007-067)**

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

Applications considered valid for the start of the assessment:

- **Calsporin® (*Bacillus subtilis*).** Zootechnical additive for chickens for fattening **(EFSA-Q-2007-040)**

  The application and the particulars related to the question on Calsporin® have been considered valid by EFSA on the 18th April 2007.

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

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

- **Kemzyme® W Dry (endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, alpha-amylase, bacillolysin and endo-1,4-beta-xylanase) Safety for laying hens (EFSA-Q-2007-073)**

  See under 5.1.

- **035 (*Bacillus subtilis*) for chickens for fattening. Compatibility with coccidiostats Safety for laying hens (EFSA-Q-2007-075)**

  The FEEDAP Panel delivered an opinion on 17 October 2006 on the safety and efficacy of this product when used as an additive for chickens for fattening.[10] In that opinion, the FEEDAP Panel was not able to give a conclusive opinion on the compatibility of this microbial preparation with some coccidiostats. The applicant has provided new studies to support compatibility.

  This application will be dealt by the WG on Micro-organisms. The deadline proposed by the European Commission is 1st June 2007.

[9] http://www.efsa.europa.eu/en/science/feedap/feedap_guidance/other_guidance_documents.html
[10] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej406_035_cff.html

8. GENERAL INFORMATION FROM EFSA

- The Scientific Co-ordinator informed the Panel that EFSA's logo has changed since 27th March.
- Several members of the Panel reported back on the various meetings they attended in other Panels and/or in the Scientific Committee.
- The Panel on Biological Hazards has set two working groups, one on "Foodborne antimicrobial resistance as a biological hazard" and the other on "Microbiological risk assessment in feedingstuffs for food-producing animals". Two Panel members will attend these WG on behalf of the FEEDAP Panel.
- A WG of the Standing Committee on Animal Health and Food Chain took place on 30th March to discuss the new guidelines for the assessment of feed additives. Some members of the Panel and the Scientific Secretariat of EFSA attended to this meeting and reported back to the Panel.
- The Plenary in May has been cancelled and substituted for several working groups. The Plenary in November has been re-scheduled due to the coincidence with the EFSA's 5th Anniversary event in Brussels. The Plenary meeting will also take place in Brussels.

9. MISCELLANEOUS

- **Presentation of the new interface for the EFSAnet**

  The Secretariat presented the Panel with the new interface and platform that will be used for the exchange of information between EFSA, its Panel members, the European Commission and Member States.

- The issue of the revision of the daily allowances and indemnities was briefly discussed in the meeting of the Management Board held in Berlin on 27 March. It will be discussed in more detail during the next Management Board meeting to be held on 19 June.