European Food Safety Authority

MINUTES OF THE 21ST PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(BRUSSELS, 15-16 JUNE 2005)

(ADOPTED BY WRITTEN PROCEDURE ON 29TH JULY 2005)

PARTICIPANTS

Panel Members:
Arturo Anadón, Margarita Arboix Arzo (2nd day), Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Noël Dierick (1st day), Jürgen Gropp, Ingrid Halle, Joop de Knecht, Anne-Katrine Lundebye Haldorsen, Alberto Mantovani (2nd day), Kimmo Peltonen, Guido Rychen (2nd day), Pascal Sanders, Amadeu Soares, Pieter Wester and Wilhelm Windisch (1st day)

Apologies
Margarita Arboix Arzo (1st day), Noël Dierick (2nd day), Gerhard Flachowsky, Anders Franklin, Alberto Mantovani (1st day), Guido Rychen (1st day) and Wilhelm Windisch (2nd day)

EFSA
Liisa Vahteristo, Claudia Roncancio, Jaume Galobart, (scientific staff), Dominique Byron (administrative staff)

European Commission
Taina Säteri, Rosella Brozzi Bettio, Almudena Rodríguez (1st day), Rui Cavaleiro (2nd day) and Marta Ponghellini (2nd day) (DG Health and Consumer Protection)

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all the participants to the 21st Plenary meeting of the FEEDAP Panel.

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

2. DECLARATIONS OF INTEREST

There were no specific interests declared. The annual declarations of interest and independence forms were distributed to all the Panel members for their renewal.

3. ADOPTION OF THE AGENDA

The agenda was adopted.

4. ADOPTION OF THE DRAFT MINUTES OF THE 20TH PLENARY MEETING ON 25-26 May 2005

The minutes of the 20th Plenary meeting of the Scientific Panel held on 25-26 May 2005 were reviewed and adopted. The previously adopted minutes of the 19th plenary meeting were distributed to all the members.

5. GENERAL INFORMATION FROM EFSA

- The consultation on the guidelines for the assessment of silage additives will be published on the EFSA website shortly. The consultation period will be open until the 15th September.
- The EFSA annual report for 2004 was distributed to the panel members.

6. WORK PROGRAM

6.1. Discussion and possible adoption of the following scientific opinions

- **Safety of the enzyme preparation Roxazyme G2 for ducks (EFSA-Q-2005-011)**

  The Rapporteur of the Working Group (WG) on Enzymes introduced the draft document. EFSA is requested to deliver an opinion on the safety of this enzymatic product, which is a preparation of endo-1,4-beta-glucanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced from *Tricoderma longibranchiatum* (ATCC 74 252), for the target animals ducks.

  The tolerance study presented by the petitioner showed that the product is well tolerated by the ducks. The opinion was adopted by the Panel following some proposed editorial changes.

- **Safety of the enzyme preparation Econase Wheat Plus for chickens for fattening (EFSA-Q-2005-010)**

  The Rapporteur of the WG on Enzymes introduced the draft document. EFSA is requested to deliver an opinion on the safety of this enzyme product, which is a preparation of endo-1, 4-beta-xylanase (IUB 3.2.1.8) from *Trichoderma reesei* CBS 529.94 and endo-1, 3(4)-beta-glucanase (IUB 3.2.1.6) from *Trichoderma reesei* CBS 526.94, for the chickens for fattening.

  The document was reviewed in detail, and it was concluded that the product is safe for the target species. The opinion was adopted subject to some minor editorial changes.

- **Safety of BioProtein: product of fermentation from natural gas (EFSA-Q-2004-171)**

  EFSA is requested to issue an opinion in the light of the concerns expressed in the most recent SCAN opinion of 14 February 2003 on the effects of BioProtein on health parameters (changes in white blood cell counts, lymph node weights, spleen and liver changes, histology changes, body weight depression), taking into consideration the new information provided by the firm.

  The rapporteur of the WG on BioProtein shortly introduced the background to the question and the draft document. The draft and the new results were reviewed in detail. In the view of the panel the few new studies presented do not alleviate the concerns for animal and human safety, as previously expressed by SCAN. This opinion was adopted after introducing minor editorial modifications.

- **Safety and efficacy of Reuteri Pig Powder for piglets (EFSA-Q-2003-010)**

The Rapporteur of the WG presented the draft opinion on micro-organism product *Lactobacillus reuteri* 1063S aimed at permanent authorisation for piglets. The draft was reviewed in detail but the panel could not conclude on the efficacy of the product based on the data presented, nor was there sufficient evidence on the safety of the product for the target species due to the design and lack of statistical treatment of the data. The opinion was adopted after introducing a few editorial changes.

- **Safety of use of colouring agents in animal nutrition – red pigmenting carotenoids (astaxanthin) (EFSA-Q-2003-060)**

  EFSA is asked to assess the safety of use of capsanthin (E160c), beta-apo-8'-carotenal (E160e), ethyl ester of beta-apo-8'carotenic acid (E160f), lutein (E161b), cryptoxanthin (E161c), zeaxanthin (E161h), citranaxanthin (E161i), astaxanthin (E161j) in feedingstuffs for laying hens, other poultry, salmon, trout, on the basis of currently available scientific literature.

  The Rapporteur of the WG on Carotenoids presented the draft document on Asthaxanthin, which included some revisions since the last plenary discussions. The document was reviewed in detail and the panel agreed to the contents of the document. The draft on the other red pigmenting carotenoids (capsanthin, citranaxanthin and cryptoxanthin) will need to be introduced and discussed as the next step to allow adoption of the first carotenoid document (red pigmenting carotenoids). Another opinion will then deal with yellow pigmenting carotenoids.

6.2. Discussion on the draft guidelines from the Commission

In a letter dated 20 May 2005, the European Commission asks for the views of EFSA on the draft "*Regulation on implementing rules and guidelines concerning applications for authorisation of feed additives in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council*". The Commission representative introduced the document and its background to the Panel, explaining the structure and highlighting the most important parts of this draft regulation. As it is established in Article 7.4 and 7.5 of Regulation (EC) No 1831/2003, EFSA is now being consulted for the establishment of the implementing rules for Article 7 and for the guidelines.

The Panel expressed their views on the document that was presented. The Panel had problems with the structure, the inadequate clarity of the approach and with the contents of this draft Regulation. In its view the current draft would not allow the Panel to undertake appropriate safety and efficacy assessment of feed additives and their use, which is the task mandated to EFSA. The Panel also considers that the current draft does not allow any flexibility which the evolution of science might call for. The Panel emphasised very much the need to work together with the Commission in order to develop a guideline which could be useful for the applicant seeking authorisation for a feed additive, and for the Panel who will be assessing the applications. The Commission representative said that the Commission will take into account the comments from EFSA. Based on the discussion it is clear that detailed input to the guidelines cannot unfortunately be provided within the time limit (October 2005) but a new structure regarding the parts of relevance to the safety and efficacy assessment would be proposed first.

6.3. Progress reports on ongoing work

Not discussed.

7. NEW REQUESTS TO EFSA RECEIVED FROM THE EUROPEAN COMMISSION

7.1. Applications submitted under Council Directive 82/471/EEC

- **Question on the safety and bioavailability of L-Lysine sulphate (EFSA-Q-2005-081)**

  The Commission asks the European Food Safety Authority to issue an opinion on the safety for the target animals, the worker, the user, the consumer and the environment and the bioavailability of L-Lysine sulphate produced by fermentation with *Corynebacterium glutamicum*. The request will be dealt by the Working Group on Amino acids. The deadline proposed by the Commission is November 2005.

7.2. Applications submitted under Directive 70/524/EEC

- **Question on the efficacy and safety of the enzyme preparation BioFeed Pro for chickens for fattening, pigs for fattening and piglets (EFSA-Q-2005-090)**

  EFSA is requested to deliver an opinion on the efficacy and the safety of the enzyme preparation of trade name "Bio feed pro", a preparation of proteinase produced by *Bacillus licheniformis* (strain DSM 9552), for the consumer, the user, for the target animal and for the environment. The request will be dealt by the Working Group on Enzymes. The deadline proposed by the Commission is December 2005.

7.3. New applications under Regulation (EC) 1831/2003

The Commission has forwarded to EFSA one new application of a feed additive seeking authorisation under Regulation (EC) No 1831/2003 since the last plenary meeting. This application is currently being checked for completeness:

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

8. MISCELLANEOUS

None