European Food Safety Authority

MINUTES OF THE 14TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (BRUSSELS, 27-28 OCTOBER 2004)

(ADOPTED ON 1ST DECEMBER 2004 FOLLOWING WRITTEN PROCEDURE)

PARTICIPANTS

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

Apologies
Arturo Anadón (2nd day), Georges Bories (1st day), Pier Sandro Cocconcelli (2nd day), Joop de Knecht (2nd day), Alberto Mantovani (2nd day), Guido Rychen (2nd day), Pascal Sanders, Amadeu Soares

Ad-Hoc Expert
Atte von Wright (1st day)

EFSA
Liisa Vahteristo, Claudia Roncancio, Jaume Galobart (scientific staff), Dominique Byron (administrative staff), Dirk Detken (2nd day)

European Commission
Taina Säteri (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 14th plenary meeting of the FEEDAP Panel.

In particular the welcome was extended to the ad-hoc expert Atte von Wright, who is the rapporteur for some of the products under discussion.

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

2. DECLARATIONS OF INTEREST

There were no specific interests declared.

3. ADOPTION OF THE AGENDA

The agenda was approved although the order was slightly modified according to the availability of the members and Rapporteurs.

4. ADOPTION OF THE DRAFT MINUTES OF THE 13TH PLENARY MEETING ON 14-15 September 2004

The minutes of the 13th Plenary meeting of the Scientific Panel held on 14-15 September 2004 were adopted. The previously adopted minutes of the 12th plenary meeting were distributed to all the members.

5. GENERAL INFORMATION FROM EFSA

The Scientific Co-ordinator (SC) gave a short overview of the developments at EFSA, as well as an update on some general issues related to all the panels.

Approximately 4000 notifications of existing products have been received so far by the Commission. The deadline for notification of existing products ends on 7 November.

A new member of scientific staff will join the FEEDAP Team by mid-December.

Some information on the Advisory Forum event (08-09 November 2004) was provided to the Panel members.

The dates of two plenaries planned for 2005 were changed. The March plenary now will take place on the 1st and 2nd of March, and the September plenary on the 21st and 22nd. The April Plenary (12-13th) is planned to take place in Parma.

The SC introduced the document "Guidance on declaration of interests" to the Panel members, for their review and comments and was briefly discussed on the second day after members had a chance to read the document. The views of Panel members will be transmitted to the Executive Director.

The Panel was informed that the update of opinion on Cycostat 66G was adopted on 1st October following the written procedure.

6. WORK PROGRAM

6.1. Discussion and possible adoption of the following scientific opinions

KDF Preservative (EFSA-Q-2004-024)

The Rapporteur of the Working Group on Preservatives introduced the draft document. The product KDF Preservative is intended for preserving industrial fish and fish by products to be used in fish meal production. Discussion was focused on the efficacy and the safety of the product. Some concerns were raised on the quality of some of the studies presented.

The Rapporteur was requested to amend the document according to the points made during the discussion. A revised document should be presented in the November Plenary.

Use of iodine in feedingstuffs (EFSA-Q-2003-058)

The Rapporteur pointed out some points that needed further discussion, such as animal welfare and health issues, potential consumer risks and various recommendations. As further inputs to the document are expected, the full discussion on this draft is likely to continue only in December.

MLB for cats (EFSA-Q-2003-115)

The Rapporteur from the Working Group on Micro-Organisms introduced the question and the draft opinion for discussion. EFSA was requested to assess the safety of this microbial product based on a strain of *Lactobacillus acidophilus* DSM 13241 for the cat, the user of the product and the environment.

The FEEDAP Panel concluded that there were no safety concerns about MLB for the target species and the environment. However, due to the lack acceptable data on the shedding of human enteropathogens by cats, the safety for the owner could not be established.

The Panel adopted the opinion after minor modifications were identified.

Bonvital for chickens for fattening (EFSA-Q-2004-027)

The Rapporteur from the Working Group on Micro-Organisms introduced the question and the draft opinion for discussion. The notifier is seeking an extension of use of this product (previously called Provita E), already authorized for use in piglets and pigs for fattening and for chickens for fattening. EFSA was requested to assess the safety of this microbial preparation based on a single strain of *Enterococcus faecium* DSM 7134. The FEEDAP Panel concluded that the product is likely to be safe for the target species, but due to poor experimental design it is not possible to reach a final conclusion on the absence of adverse effects due to changes in the intestinal microflora.

The opinion was adopted after discussion provided few editorial changes were incorporated.

Avizyme 1210 for turkeys for fattening (EFSA-Q-2004-067)

EFSA was requested to assess the safety of this product for turkeys for fattening and to examine if it is necessary to revise the safety for humans, users and environment previously evaluated by the SCAN. The Rapporteur of the Working Group on Enzymes introduced the draft opinion. After a short discussion the FEEDAP Panel agreed that the product can be considered safe for the target species and confirmed the validity of the previous SCAN opinion regarding other safety aspects.

The opinion was adopted after few editorial modifications.

Kemzyme W Dry (EFSA-Q-2004-111)

EFSA has been requested to assess the safety of this enzyme preparation consisting of endo-1,3(4)-β-glucanase produced by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-β-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94), α-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) and endo-1,4-β-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842) in particular regarding the ability of the *Bacillus* producing strains to produce toxins.

The draft opinion was introduced to the Panel. The Notifier is responsible only for the blending of the product and has relied on the primary producer for data on the Bacillus spp. Since another blended product containing enzymes from *Bacillus amyloliquefaciens* has already been evaluated based on this data and accepted by the Panel, the Chair invited comments on the circulated draft opinion within 10 days and suggested that the adoption should then take place by written procedure. This procedure was accepted by the Panel members.

Zeolite A (EFSA-Q-2003-019)

The Rapporteur introduced the question and the draft opinion to the Panel members. EFSA is requested to assess the safety of Zeolite A (synthetic sodium aluminum silicate) for the animals, humans and the environment. The submission has been done in order to modify Directive 93/74/EEC on feedingstuffs intended for particular nutritional purposes.

The document was discussed for the first time. After few changes it will be presented for adoption at the November Plenary.

Safety of 4-Nitrophenylarsonic acid (EFSA-Q-2003-014)

The rapporteur of the Working Group introduced the new draft document. All the different sections were reviewed in detail and further discussion was held on the safety of this compound in the framework of a preliminary assessment. Due to the absence of a complete set of toxicological and metabolic data on the pathways of 4-nitrophenylarsonic acid in laboratory animals and target species, it was not possible to establish a NOEL, an acceptable ADI or an MRL value. The panel adopted the opinion subject to some editorial changes.

6.2. Progress reports on ongoing work

Not discussed.

7. NEW REQUESTS TO EFSA RECEIVED FROM THE EUROPEAN COMMISSION

- Question on Clinacox for rabbits for fattening and breeding (EFSA-Q-2004-147)

The Commission asks the European Food Safety Authority to deliver an opinion on the safety and efficacy of the product "Clinacox 0.5%" based on diclazuril, for rabbits for fattening and breeding. The request will be dealt by a new WG. The deadline proposed by the Commission for the assessment is April 2005.

- Question on Aquasta for salmon and trout (EFSA-Q-2004-148)

The Commission requests the European Food Safety Authority to issue an opinion on the efficacy and on the safety the product "Aquasta" based on Astaxanthin-rich *Phaffia rhodozyma* ATCC SD-5340, for trout and salmon. The request will be dealt within an existing WG on Astaxanthin-rich products. The deadline proposed by the Commission for the assessment is April 2005.

- Question on Farmatan for rabbits and piglets (EFSA-Q-2004-149)

The Commission asks the European Food Safety Authority to deliver an opinion on the safety and efficacy of the product "Farmatan" based on *tannin*, for rabbits and piglets. The request will be dealt within a new WG on Tannin. The deadline proposed by the Commission for the assessment is April 2004.

EFSA has not received the relevant documentation (dossiers) for none of the products and questions listed above. Therefore, EFSA has not yet formally been in a position to consider the acceptance of the requests nor the proposed deadlines. Consequently, modifications to the above stated requests might occur. The three applications are submitted according to Directive 70/524/EEC with a Member State Rapporteur identified for each. No applications have yet been submitted to EFSA according to Regulation 1831/2003, which is being applied since 18 October 2004.

8. FEEDBACK FROM THE SCIENTIFIC COMMITTEE HELD ON 13-14TH OCTOBER 2004

Not discussed.

9. MISCELLANEOUS

None.