MINUTES OF THE 10TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (BARCELONA, 5-6-7 MAY 2004)

ADOPTED ON 7 JUNE 2004

PARTICIPANTS

Panel Members:
Arturo Anadón, Margarita Arboix Arzo, Georges Bories, Paul Brantom, Joaquim Brufau de Barbera, Andrew Chesson, Pier Sandro Cocconcelli, Gerhard Flachowsky, Anne-Katrine Haldorsen, Joop de Knecht, Noël Dierick, Anders Franklin, Jürgen Gropp, Ingrid Halle, Alberto Mantovani, Kimmo Peltonen, Guido Rychen, Pascal Sanders

Apologies
Anders Franklin (1st day), Alberto Mantovani (3rd day), Pieter Wester

EFSA
Herman Koëter (Head of Science), Liisa Vahteristo, Sandrine Valentin, Jaume Galobart (scientific staff), Victoria Villamar (International & Institutional Affairs), Dominique Byron (administrative staff)

European Commission
Marta Ponghellini (2nd day), Montserrat Tortades Baucells (3rd day)

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1. WELCOME AND APOLOGIES FOR ABSENCE

The chair opened the meeting and welcomed all the participants to the 10th plenary meeting of the FEEDAP Panel. Members not able to attend the meeting had sent their apologies (see under participants). The chair informed the Panel that Prof Leibetseder had resigned from this Panel and thanked him for his fruitful contribution to the work of FEEDAP Panel.

The Director of "Casa de Convalescencia centre" welcomed the FEEDAP Panel to its first Plenary Meeting out of Brussels. The authorities thank EFSA for the opportunity given to organize this meeting in the facilities of the Casa de Convalescencia centre and pointed out the relevance of this event.

2. DECLARATIONS OF INTEREST

Dr Brufau de Barbera informed the Panel that his department was involved in studies for products Biofeed phytase and Toyocerin and proposed therefore not to participate to the debate on that product.

3. ADOPTION OF THE AGENDA

The agenda was approved.

4. ADOPTION OF THE DRAFT MINUTES OF THE 9TH PLENARY MEETING ON 3-4/03/2004

The minutes of the 9th Plenary meeting of the Scientific Panel held on 14-15 April 2004 were adopted. The previously adopted minutes of the 8th plenary meeting have been distributed to all the members previously by email.

5. GENERAL INFORMATION FROM EFSA

Concerning the call for expression of interest for additional experts to the scientific panels, short list should be finalised in May and will be forward to the Advisory Forum. Following the feedback from the Advisory Forum, a final list will be submitted to the Management board for adoption in the end of June.

The Panel was informed that the annual declarations will be collect during the next Plenary meeting.

6. WORK PROGRAM

6.1. Discussion and possible adoption of the following scientific opinions

Re-evaluation of coccidiostat Cycostat in accordance with article 9G of Directive 70/524/EEC

The Rapporteur of the Working Group introduced the draft document. The introduction and safety chapters (except tolerance and microbiological parts) were reviewed in detail. The Rapporteur was requested to amend these parts. Due to lack of time, it was not possible to complete the discussion on Cycostat draft. It will be put in the agenda of the next Plenary meeting.

Coccidiostat Kokcisan

The Rapporteur of the Working Group introduced the draft to the plenary. The Panel reviewed the report in detail. It was felt appropriate to introduce in the draft a short paragraph concerning the fact that companies (which apply for Brand Specific Approval for the same active substance: salinomycin sodium) have been contacted to obtain their agreement to merge some specific data which is not product dependent. This paragraph will be included in the two other opinions concerned. The Panel adopted the opinion after discussion provided that some editorial changes were incorporated.

Micro-organisms Products:

- Toyocerin for pigs for fattening

The draft document was briefly introduced by the Rapporteur of the Working Group (WG) on Micro-organisms. The Panel reviewed the report and after a short discussion, the opinion was adopted subject to some editorial changes. It has been concluded that the product Toyocerin® can be efficacious when added to feeds for pigs for fattening within the dose ranged proposed and when used over the entire fattening period.

Enzymes Products:

- Bio Feed Phytase – change of strain

The Rapporteur from the Working Group on Enzymes introduced the question and the draft opinion for discussion. The Panel reviewed the draft in detail. Some amendments were requested by the Panel on the characterisation of the product, the user and consumer part and the environmental part. A revised final draft of the document will be circulated shortly and adoption should then take place by written procedure.

Product Nutrigrow as a source of protein for pigs for fattening

Not discussed.

6.2. Progress reports on ongoing work

Not discussed due to lack of time.

7. NEW QUESTIONS RECEIVED FROM THE EUROPEAN COMMISSION

- Question on Hy D (calcifediol) for chickens for fattening, turkeys, laying hens (EFSA-Q-2004-065)

The Commission asks the European Food Safety Authority to issue an opinion on the safety for consumer, target species, user and environment and on the efficacy of the product. A new Working Group will be established to address this question, same experts to this WG were already identified. The deadline proposed by the Commission for the assessment is September 2004. The expected completion date is approximately half a year from the date all the data has been received.

- Question on Bio Feed Alpha CT and L for chickens for fattening (EFSA-Q-2004-069)

The Commission asks the European Food Safety Authority to issue an opinion on the safety of the enzyme preparation of trade name "Bio Feed Alpha CT and L" preparation of alpha-amylase, EC 3.2.1.1, and endo-1,3(4)-beta-glucanase, EC 3.2.1.6, produced by *Bacillus amyloliquefaciens* (DSM 9553)" in particular regarding the ability of the producing strain to produce toxins under the conditions of use requested by the applicant company. The deadline proposed by the Commission for the assessment is August 2004.

- Question on Bio Feed Phytase for salmonids (EFSA-Q-2004-070)

The Commission asks the European Food Safety Authority to issue an opinion on the safety for consumer, target species, user and environment of the product produced by the new manufacturing process. The request will be dealt within the WG on Enzymes. The deadline proposed by the Commission for the assessment is July 2004.

8. FEEDAP PANEL "MEETS THE STAKEHOLDERS" - OPEN SESSION ON THE 6TH MAY 2004

See Annex 1.

9. MISCELLANEOUS

- The next Plenary meeting is confirmed to take place on the 7th-8th June 2004.
- The work of CONTAM Panel continues on undesirable substances. Two members were nominated to be representatives of FEEDAP Panel as the one nominated previously has resigned. Depending on the topic also other experts of the Panel continue to work with the CONTAM Panel.

ANNEX 1: FEEDAP PANEL "MEETS THE STAKEHOLDERS" - OPEN SESSION ON THE 6TH MAY 2004

Background

The European Food Safety Authority (EFSA) invited stakeholders including authorities, consumer and industry associations and their members to meet with EFSA's Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) in a Special Informative Session of the Panel in the context of its 10th Plenary Meeting.

The purpose of the special informative session was for the Panel to hear the views and concerns from competent authorities and stakeholders on issues related to the new Regulation (EC) No 1831/2003 on additives for use in animal nutrition.

Audience

The FEEDAP Open session attracted approx. 80 participant from various stakeholders. Largest proportion of participants came from industry with representatives from a range of companies dealing in animal nutrition field. Industry associations (European, national and local ones) were also well represented. Besides, governmental authorities dealing with food safety, other associations, universities, research institutes and consumers were also represented.

Introduction

Dr. Herman Koëter, Deputy Executive Director of the European Food Safety Authority and Director of Science, welcomed the participants to the Open Session and opened the meeting with an introduction to the European Food Safety Authority.

Prof Andrew Chesson, Chair of FEEDAP Panel, gave a short overview of the Work and the Scope of the FEEDAP Panel and introduced the new feed additives Regulation (EC) No 1831/2003 which gives a number of important changes to Directive 70/524/ECC currently governing the Community authorisation of additives for animal nutrition. Prof Chesson highlighted that in the coming months, EFSA through its FEEDAP Panel will need to develop a number of guidance documents in relation to the new Regulation to help petitioners develop the requested data sets.

Question/Discussion

Several points for discussion were raised by 16 organisations or participants in writing before the Open Session. They were used as the basis for structuring the meeting.

Dr Didier Jans, Secretary General of FEFANA (European Federation of the Animal Feed Additive Manufacturers), introduced concerns from FEFANA on the new Regulation (EC) No 1831/2003 (and especially on the notification form for which FEFANA prepared a notification guidelines for industry) and on the need for guidelines for the new categories of additives (silages additives, plants extracts...).

Communication and transparency, confidentiality

Concerns about the lack of communication and of confidentiality have been expressed. Applicants would like to have an opportunity of dialogue with the scientific experts before the publication of opinion and are worried about the level of detail and the amount of confidential information published on the EFSA Web site in the full assessment report/(EFSA's opinion).

EFSA: Communication between the applicant and the FEEDAP Panel are possible through the FEEDAP Panel's secretariat which can address any request from companies to the Panel. It is also possible for applicants to ask for a hearing by the Panel if the dossier needs a special introduction. FEEDAP Panel can also address any request to the applicant through the FEEDAP secretariat when some information in the dossier is missing. the Panel may also invite the applicant to a hearing by the Panel.

Concerning the confidentiality, EFSA will try to harmonize the level of confidentiality between the different Panels and to maintain the transparency required. In all cases, opinions should provided sufficient amount of information to justify the position of the Panel on the level of safety.

Self tasking

The FEEDAP Panel has included self tasking in its work programme. One of them concerns an update of the SCAN Opinion on the criteria used in the assessment of bacteria for resistance to antibiotics of human or veterinary importance. More information was requested from the FEEDAP Panel on this topic.

The Rapporteur of the self tasking informed the participants that more information on the resistance to antibiotics has became available since SCAN Opinion and therefore it is relevant to revise the values based on the scientific literature and to have a better understanding of the potential of transfert of genes from one strain to another.

Harmonized MRL

Article 9.7 of the new Regulation (EC) No 1831/2003 underlines that 'Where the levels of residues of an additive in food from animals fed with that additive might have a detrimental effect on human health, the Regulation [granting authorisation for a feed additive] shall include MRLs for the active substance or for its metabolites in the relevant foodstuffs of animal origin.'

Two experts of FEEDAP Panel mentioned in response to a general concern about setting MRLs for all foods that the process of determination of MRLs should be harmonized between the bodies which establish MRLs in the European Union.

Undesirable substances in feed additives

Question on the analytical methodology for evaluating risk assessment regarding undesirable substances in mineral feed additives was raised.

FEEDAP Panel felt that any method used to determine the level of undesirable substances in mineral feed additives is acceptable in principal if it has been demonstrated that the method was relevant, scientifically validated and reproducible.

Efficacy

A concern on the high quality level of efficacy studies required for an EU approval and the lack of flexibility in experimatal studies was expressed. A question on the relevance of the *in vitro*/*in vivo* studies was also addressed to the Panel.

The FEEDAP Panel is aware with the high level of quality requirements of efficacy studies and even sometimes the lack of flexibility. Concerning the relevance of the *in vitro*/*in vivo* studies, FEEDAP Panel is not in a position, at this stage, to define the most appropriate system suitable to demonstrate the efficacy of an additive.

Natural/herbal products

FEEDAP Panel was asked to give more information concerning the level of information requested when natural/herbal products are considered as feed additives for authorisation.

FEEDAP Panel informed that a self tasking on the assessment of herbs, essential oils and other plants products as "additives" for use in animal nutrition should be included in the work program of FEEDAP in order to develop a guidance document.

Mineral/Trace elements

FEEDAP Panel was asked about the level of proof requested to demonstrate the safety and efficacy of mineral elements used in animal nutrition but which represent a small tonnage in feed industry and if a simplified procedure could be considered in reevaluations.

FEEDAP Panel informed proof of efficacy of this type of additives could be given through the literature and more information could be requested on environmental impact rather than on efficacy.

Before closing the Open session, Dr Herman Koëter thanked the audience for its kind participation to the Open session and Spanish hosts for the facilities provided to organize this meeting and lastly the FEEDAP Panel and its secretariat.