European Food Safety Authority

MINUTES OF THE 3RD PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (BRUSSELS, 9-10 SEPTEMBER 2003)

(ADOPTED ON 22 OCTOBER 2003)

PARTICIPANTS

Panel Members:
Arturo Anadón (1st day), Margarita Arboix Arzo, Georges Bories, Joaquim Brufau de Barbera, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Noël Dierick (1st day), Gerhard Flachowsky, Anders Franklin, Jürgen Gropp, Anne-Katrine Haldorsen, Ingrid Halle, Josef Leibetseder, Kimmo Peltonen, Guido Rychen, Pascal Sanders, Pieter Wester

Apologies
Arturo Anadón (2nd day), Paul Brantom, Noël Dierick (2nd day), Alberto Mantovani

EFSA
Marie-Nöelle Costa (administrative secretary of FEEDAP Panel), Liisa Vahteristo (scientific co-ordinator of FEEDAP Panel)

European Commission
Miguel Granero Rosell, Marta Ponghellini, Montserrat Tortades Baucells, Eric Thévenard (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 3rd 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 approved after some rearrangements in the order.

3. DECLARATIONS OF INTEREST

No specific interests relevant to the items on the agenda were declared.

4. MINUTES FROM THE PREVIOUS MEETING

The minutes of the second plenary meeting of the Scientific Panel held on 8th and 9th July 2003 were adopted. The adopted minutes of the inaugural meeting were distributed to all members.

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5. GENERAL INFORMATION FROM EFSA

The Scientific Co-ordinator gave a short overview of the developments of EFSA and its staff, as well an update on some general issues related to all the panels. The panel was informed about the Colloque EFSA is organising in Ostend, Belgium, in October, which is organised to start the dialogue with its stakeholders. All the Chairs of the Panels are invited to take part. The panel was also informed that EFSA is preparing notes for all the panel members concerning how to handle media contacts. In addition, the chairs of the Panels and the Scientific Committee will be offered media training this year, a second opportunity for training is forseen in the spring.

6. SCHEDULE OF PLENARY MEETINGS

Another two-day plenary meeting in November and an extension of the December plenary to a third day was proposed as the work program of the FEEDAP Panel is extensive with several pending deadlines. After discussion the Panel agreed to hold a plenary meetings on 22-23 October (as previously agreed), 12-13th November and 2-3-4th December 2003.

The schedule of plenary meetings for 2004 was discussed and the Panel agreed to hold seven two-day plenaries in 2004, but the dates could only be provisionally adopted and should be confirmed.

7. FEED-BACK FROM THE SCIENTIFIC COMMITTEE

The Chair briefly described the outcome of discussions concerning among other things the developments on QPS (Qualified Presumption of Safety) document and the format of scientific opinions of EFSA. Details of all the discussions can be found on the web page of EFSA under Scientific Committee.

8. WORK PROGRAMME

8.1. Discussion and possible adoption of scientific opinions

8.1.1. Reevaluation of coccidiostat Stenorol (halofuginone hydrobromide) in accordance with article 9G of Directive 70/524/EEC

The Rapporteur of the Working Group introduced the draft document amended since the first discussion during the previous plenary meeting on this product. The Panel reviewed the report in detail and agreed to the general approach and structure presented. Number of issues which are relevant for all the other reevaluations of coccidiostats were extensively discussed. Some clarifications were requested from the Working Group. The draft summary and conclusions were shortly discussed in general terms. A revised document should be presented in the October plenary.

8.1.2. Reevaluation of coccidiostat Koffogran (nicarbazin)

A draft document was presented to the Panel by the Rapporteur. In view of the time necessary for a proper discussion, the detailed discussion was postponed to the next plenary meeting. The rapporteur was requested to amend the document according to the points made during general discussion and some more specific remarks made on this draft opinion.

8.1.3. Safety of the enzymatic product Avizyme 1300® for laying hens

The Rapporteur presented the draft opinion from the Working Group on Enzymes. The WG on Micro-Organisms had also been involved in the evaluation concerning toxin production aspects. The draft report includes aspects on safety as the request is for an extension of use of this product to another animal category: laying hens. It was concluded that the Avizyme 1300 is safe for use in laying hens. The Panel unanimously adopted its first scientific opinion after some agreed minor modifications.

8.2. Progress Reports

8.2.1. Reevaluation of coccidiostats in accordance with article 9G of Directive 70/524/EEC

Avatec (lasalocid sodium)

The Working Group met in early September and identified areas which need to be reevaluated due to very recent submission of complementary data.

Cycostat 66G (robenidine hydrochloride)

See under 10.

Deccox (decoquinate)

First meeting of the Working Group is scheduled for September.

Elancoban (monensin sodium)

Work plan is under progress but no meetings agreed yet.

Monteban (narasin)

The draft is not yet finalised and potentially another Working Group meeting is needed.

Sacox 120 microGranulate (salinomycin sodium)

Work is under progress but no date for a meeting is scheduled yet.

8.2.2. Coccidiostats

Kokcisan 120G (salinomycin sodium)

Work is under progress but no date for a meeting is scheduled yet.

Efficacy of SACOX 120 (salinomycin sodium) at 30-50 mg/kg

Not discussed.

8.2.3. Questions on products of Micro-organisms

Each of the products

- Turval B0399 (*Kluyveromyces marxianus-fragilis)* for weanling piglets
- Biomin BBSH 797 (*Eubacterium sp.)* for piglets, pigs for fattening and chickens for fattening
- Biosprint BCCM / MUCL 39885 (*Saccaromyces cerevisiae*) for dairy cattle
- YeaSacc (*Saccaromyces cerevisiae*) for leisure horses
- MLB (*L. acidophilus*) for dogs

were discussed at a working group meeting in August. A Rapporteur for each question were nominated and progress on the evaluations are made. Next meeting is scheduled for October.

8.2.4. Questions on Enzymes

The product Natuphos for the ducks, the geese, the salmonidae and the channel catfish was discussed at a working group meeting in early September but no Rapporteur for the product was nominated as some clarification concerning the terms of reference and the status of the product was needed. Another working group meeting for enzyme products is scheduled for November.

8.2.5. Question on the safety of use of iodine in feedingstuffs

First Working Group meeting is planned for October 21st.

8.2.6. Question on use of the synthetic sodium aluminium silicate (zeolite) for the reduction of risk of milk fever in diary cows

Three panel members have received the data provided together with the request for opinion in order to plan further steps needed in the assessment.

8.2.7. Question on assessment of the safety of all carotenoids authorised in 70/254

Not discussed.

9. NEW QUESTIONS

EFSA had received five new questions from the Commission which have been allocated to the FEEDAP Panel.

9.1. Question on micro-organism product BioPlus 2B for chickens for fattening, turkeys for fattening

The Commission asks the European Food Safety Authority to deliver an opinion on the impact of the mixing of the micro-organism product Bioplus 2B with coccidiostat maduramicin ammonium and on the safety of Bioplus 2B when used under proposed conditions, taking into account the information submitted by the applicant in the dossier. The request will be dealt with the Working Group (WG) on Micro-Organisms. The deadline proposed by the Commission for the assesment is before February 2004.

9.2. Question on microorganism product Reuteri Pig Powder

The Commission asks the European Food Safety Authority to deliver an opinion on the safety of micro-organism product Reuteri Pig Powder, for the target animals, the human consumer, the user of the product and the environment, and on its efficacy, taking into account the information submitted by the applicant in the dossier.

Proposed deadline for the assessment is before November 2003. The request will be dealt with the Working Group (WG) on Micro-Organisms, but neither EFSA nor the WG members have yet received the dossier from the applicant.

9.3. Question on the enzyme preparation Finase for laying hens, turkeys for fattening, sows

The Commission asks the European Food Safety Authority to deliver an opinion on the safety and efficacy of this enzyme preparation as feed additive, under proposed conditions of use.

Proposed deadline for the assessment is May 2004. The request will be dealt with the WG on Enzymes.

9.4. Question on the safety of the change of strain of the producing micro-organism of the enzyme preparation Bio Feed Phytase

The Commission asks the European Food Safety Authority to deliver an opinion on the safety to the consumer, the target animal categories (Chickens for fattening, laying hens, turkeys for fattening, piglets and pigs for fattening, and sows) and the environment of the change of strain of the producing micro-organism of the enzyme preparation Bio Feed Phytase, from the currently authorised DSM 11857 to the new, genetically modified, strain DSM 14223, taking into account the information submitted by the applicant in the dossier. The request will be dealt with the WG on Enzymes of the FEEDAP Panel.

9.5. Question on coccidiostat Bio-Cox 120G for chickens for fattening

The Commission asks the European Food Safety Authority to issue an opinion on the safety and the efficacy of product Bio-Cox 120G, when used under proposed conditions of use, taking

into account the background and the information submitted by the applicant in the dossier. In doing so, EFSA is asked to address and answer the following questions:

- Is the use of BIO-COX 120 G as an additive safe for the consumer? In particular
- Does the proposed use result in residues in meat? If so, what is the qualitative and quantitative composition of these residues?
- Is the development of antimicrobial resistance possible?
- Is its utilisation safe for the target species, the user and the environment?
- Has the use of BIO-COX 120 G significant effects on the prevention of coccidiosis in chickens for fattening?

Proposed deadline for the assessment is December 2003.

10. ORGANISATION OF WORKING GROUPS

In accordance with the current work programme a new working group was created for the reevaluation of coccidiostat Cycostat 66G (robenidine hydrochloride) and for the evaluation of Bio-Cox 120G (salinomycin sodium).

11. ANY OTHER BUSINESS

The possibility for self tasking was shortly discussed and it was agreed the EFSA secretariat would circulate to the Panel all proposals received from the members in order to have a discussion on potential topics in the next plenary. In case an issue is proposed for self-tasking then background and terms of reference should be prepared by the Panel to be proposed to EFSA.