MINUTES OF THE 2ND PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (BRUSSELS, 8-9 JULY 2003)

(ADOPTED ON 9TH SEPTEMBER 2003)

PARTICIPANTS

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

Apologies
Arturo Anadón (2nd day), Margarita Arboix Arzo (2nd day), Joaquim Brufau de Barberà (1st day), Pier Sandro Cocconcelli, Pieter Wester

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

European Commission
Miguel Granero, Eric Thévenard (DG Health and Consumer Protection)

1. WELCOME AND APOLOGIES FOR ABSENCE

The chair opened the meeting and welcomed all the participants to the 2nd plenary meeting of the FEEDAP Panel. Few members not able to attend the meeting had send their apologies (see under participants).

2. ADOPTION OF THE AGENDA

The agenda was approved after few modifications which are reflected in the minutes of the meeting.

3. DECLARATIONS OF INTEREST

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

4. MINUTES FROM THE PREVIOUS MEETING

The minutes of the inaugural meeting of the Scientific Panel held on 21st May 2003 were adopted subject to incorporation of a few changes proposed by the Panel.

5. GENERAL INFORMATION FROM EFSA

The Scientific Co-ordinator shortly described the current status and future prospects concerning the number of staff, office location in Brussels and the start of scientific activities of EFSA. The Panel was also informed about the decision by the Management Board concerning Access to documents.

6. FEED-BACK FROM THE SCIENTIFIC COMMITTEE

The chair informed the Panel about the outcomes of the first meeting of the Scientific Committee (SC) which took place on 30 June and 1 July. Professor Vittorio Silano (I) was elected as Chair. Dr. Ada Knaap (NL) and Dr. Pierre Le Neindre (F) were elected as Vice-Chairs.

The SC had discussed the flow of requests for scientific advice from the Commission to the Scientific Committee and Panels of the EFSA and ways to ensure a good interaction between the Scientific Panels and the Committee. The Committee also asked for advice from the Panels on a general format for opinions expressed by the EFSA Panels and Committee and on other possible issues to be addressed by the Scientific Committee. It also wished to involve the Panel members on a practical guidance to be provided by the EFSA about how to handle declarations of interest. The views and needs expressed by the members of the Panels will be taken into consideration in the preparation of a guidance document on declarations of interest. It is foreseen to discuss this EFSA proposal at one of the next plenary meetings of the SC.

7. WORK PROGRAMME

7.1. Discussion of the following scientific opinions:

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

The Scientific Panel on Additives and Products or Substances used in Animal Feed is requested to consider each coccidiostat under reevaluation (Decoquinate (DECCOX®), Halofuginone (STENOROL®), Lasalocid sodium (AVATEC 15%®), Monensin sodium (ELANCOBAN®), Narasin (MONTEBAN®), Salinomycin sodium (SACOX 120 micro-Granulate®), Robenidine hydrochloride (CYCOSTAT 66G®)) and to advise the Commission on their efficacy and their safety. In assessing each of the products on the basis of the dossiers presented, the Panel is requested to answer the following questions.
Under the conditions proposed for its use as additive in feed,

- Is the efficacy of the product demonstrated?
- For each product, can its use result in the development of resistance in bacteria to prophylactic or therapeutic preparations?
- Are the product and its metabolites safe for the target animals, the user, the consumers and the environment ?
- Can each product be monitored ?

Three draft documents were presented in this context:
- Avatec (Lasalocid sodium) authorised before 1988
- Monteban (Narasin) authorised before 1988
- Stenorol (Halofuginone) authorised before 1988

For each product a working group had met in June and the Rapporteurs presented shortly the main points of the assessment to the Plenary. The working groups had received working documents transferred from the Scientific Committee on Animal Nutrition and had used them as a starting point in the evaluation. The Panel discussed the issues which should be emphasised as the question is a reevaluation of already authorised substances. As these documents are the first ones of a series of coccidiostat reevaluations it was felt important to follow the same principles for all products and to keep similar structure for the documents. As a consequence, the discussion was not detailed on any of the document presented.

7.2. Status of other questions addressed to the Panel

The following other questions with the terms of reference have been transferred to the EFSA from the Scientific Committee on Animal Nutrition and are now addressed to the Scientific Panel on Additives and Products or Substances used in Animal Feed.

Reevaluation of certain additives in accordance with article 9G of Directive 70/524/EEC and reevaluation of coccidiostat Koffogran

Coccidiostats DECCOX®, ELANCOBAN®, SACOX 120 micro-granulate®, CYCOSTAT 66G® and KOFFOGRAN were discussed in relation to organising working groups (see under 8).

Coccidiostats

The questions on coccidiostat KOKCISAN® 120G (salinomycin sodium) was discussed in relation to organising working groups (see under 8). The Scientific Panel on Additives and Products or Substances used in Animal Feed is requested to advise the Commission if, :

- the efficacy of the product is demonstrated?
- the safety of the product and its metabolites is demonstrated for the target animal "chickens for fattening", the user, the consumers and the environment?
- its use can result in the development of resistance in bacteria to prophylactic or therapeutic preparations?
- it can be monitored?

The question on the efficacy of SACOX 120 (salinomycin sodium) at 30-50 mg/kg was not discussed.

Questions on products of Micro-organisms

Five questions have been transferred to the EFSA from the Scientific Committee on Animal Nutrition. Those include the following:

- Safety of micro-organism product Turval B0399 (*Kluyveromyces marxianus-fragilis)* for the target animal weanling piglets, for the user, for the consumer, for the environment
- Safety of micro-organism product Biomin BBSH 797 (*Eubacterium sp.)* for target animals piglets, the pigs for fattening and chickens for fattening, for the user, the consumer of animal products and the environment
- Safety of micro-organism product Biosprint BCCM / MUCL 39885 (*Saccaromyces cerevisiae*) for the dairy cattle, the user, the consumer of animal products and the environment
- Safety of micro-organism product YeaSacc (*Saccaromyces cerevisiae*) for leisure horses, the user, the consumer of animal products and the environment
- Safety of micro-organism product MLB (*L. acidophilus*) for the dog, the user, the owner of the animal and the environment

The questions will be addressed by the Working Group on Micro-organisms of the FEEDAP Panel.

Questions on Enzymes

Two questions on enzymes have been transferred to the EFSA from the Scientific Committee on Animal Nutrition. Those include the following:

- Safety of the enzymatic product Avizyme 1300® for the laying hens
- Safety of enzymatic product Natuphos for the ducks, the geese, the salmonidae and the channel catfish

The questions will be addressed by the Working Group on Enzymes of the FEEDAP Panel.

Question on the safety of use of iodine in feedingstuffs

The Panel is requested to issue an opinion to assess

- What are the real physiological requirements for Iodine of the different animal species referred to in Directive 70/524/EEC in regard to this trace element?
- Does Iodine, used at the current levels authorised under Directive 70/524/EC, have detrimental effect on human or animal health or on the environment?

First Working Group meeting is planned for October.

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

The Commissions requests EFSA (The Scientific Panel on Additives and Products or Substances used in Animal Feed) to assess if zeolite, when used at the levels recommended at levels recommended by the applicant (daily intake of 500-1000g of zeolite to pregnant dairy cows during the last 2-4 weeks of dry period), have detrimental effect on human or animal health or on the environment?

The question was not discussed further.

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

The Scientific Panel on Additives and Products or Substances used in Animal Feed is asked by the Commission 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. In making its assessment, the panel on feed additives is requested to prioritise the substances which may be used as alternatives to canthaxanthin.
The question was not discussed further.

8. ORGANISATION OF WORKING GROUPS

In accordance with the current work programme three working groups had been created after the last plenary in consultation with the Chair of the working group, the Chair and Panel members. Those were working groups dedicated for the reevaluation of coccidiostats in accordance with Article 9G of Directive 70/524/EEC, namely for Avatec 15% (lasalocid sodium), Monteban (narasin) and Stenorol (halofuginone). Five more working groups involved in coccidiostats evaluation were created in the plenary meeting pending acceptance from the identified external experts. New working groups were created for the reevaluation of coccidiostats Deccox (decoquinate), Elancoban (monensin sodium), Sacox 120 (salinomycin sodium) and Koffogran (nicarbazin), in addition one working group was created to assess the data submitted concerning the product Kokcisan 120G (salinomycin sodium).

For two other questions on coccidiostats (Efficacy of product Saccox at the dose of 30 ppm and Reevaluation of coccidiostat Cycostat 66G) no working groups were created due to lack of time.

Two, possibly three working group meetings on coccidiostats were agreed to be held in the course of September.

9. NEW QUESTIONS

Some new questions, mainly in connection with the Council Directive 70/524/EEC, are expected to arrive from the Commission in the near future.

10. EFSA PROPOSAL ON FORMAT OF OPINIONS

The Panel discussed the proposed format for the expression of EFSA opinions. Comments of the Panels will collected by the EFSA secretariat and brought forward to the meeting of the Scientific Committee on 27 and 28 August.

11. ANY OTHER BUSINESS

The panel discussed the need for interaction with other Scientific Panels. The Panel on Genetically Modified Organisms (GMO Panel) had identified a potential requirement to strengthen their expertise by involving experts from the FEEDAP Panel. Prof. Flachowsky was

identified as a contact/reference point of the Panel for such issues. For questions expected from The Commission concerning undesirable substances and their risk assessment the Panel on Contaminants in the Food Chain (CONTAM Panel) might wish to interact with the FEEDAP Panel to widen their expertise. Different ways for possible collaboration were discussed and Prof. Leibetseder was nominated as a reference person for such requests.

The possibility for self tasking was shortly discussed and the Panel was suggested that such proposals should be made via the EFSA secretariat.