Summary Record of the 116th SCAN Plenary Meeting , Brussels, 4-5 June 1998
(approved at the 117th meeting on 09-10 July 1998)

1. WELCOME, APOLOGIES

See presence list attached.

2. DECLARATIONS OF INTERESTS

No specific interests which might be prejudicial to the independence of the members in relation to items under discussion were declared.

3. APPROVAL OF THE AGENDA

Question 85 on the safety of use the micro-organism additives listed in notice 96/263 (O.J. N° C263, 11.9.96, p.3) following Article 5 of Council Directive 93/113/EC (O.J. N° L334, 31.12.93, p.17) was moved from point 9.1 (discussion) to point 8.4 (discussion and possible adoption) of the draft agenda. The order of the agenda was changed with the aim of better responding to priorities.

The agenda, as amended, was adopted.

4. APPROVAL OF THE SUMMARY RECORD OF THE 115 TH MEETING

The report was approved subject to a small amendment in point 10.4.

5. AT THE REQUEST OF THE COMMITTEE: DISCUSSION OF THE INTERNAL RULES OF PROCEDURE

Postponed

6. FEED-BACK BY THE CHAIRMAN ON SUBJECTS DISCUSSED IN THE SSC AND HAVING AN INTEREST FOR SCAN

Postponed

7. FEED-BACK BY MEMBERS OF SCAN HAVING ATTENDED WORKING GROUP MEETINGS OF OTHER SCIENTIFIC COMMITTEES

Postponed

8. DISCUSSION AND POSSIBLE ADOPTION OF A SCIENTIFIC OPINION CONCERNING:

8.1) Question 87 on the re-evaluation of the safety of use of nitroimidazoles as feed additives (ronidazole, ipronidazole & dimetridazole)

The members of the working group will examine the new draft for a scientific opinion that was prepared by the rapporteur and submitted to the secretariat on 3 June. The members of the working group agreed to keep in touch in order to elaborate a final draft which will be circulated to the members of the Committee in view of its discussion and possible adoption at the next plenary.

8.2) Question 91 on the re-evaluation of the safety of use of quinoxaline-n-dioxides (carbadox, olaquindox)

The chairman reminded the Committee that it had been agreed at the previous plenary that members had to address their comments in writing to the rapporteur and to the secretariat in order to enable the latter to circulate the amended draft to the members before the plenary. The rapporteur informed the Committee that only few comments were received.

A member explained that because of the fundamental nature of his comments and the number of points of disagreement he had not been able to respect the above procedure.

The SCAN discussed in detail the various aspects that are considered in the draft report which took into account the comments expressed in the last plenary. It was recognised that part of the question is going beyond risk assessment and involving risk management aspects. SCAN was asked to concentrate on the risk assessment and to clearly quantify the risk whenever this is possible.

Having reviewed the whole draft report, the chairman asked the rapporteur to incorporate the changes agreed upon as soon as possible in a final draft to be circulated to the members of SCAN before the next plenary with a view to its adoption.

8.3) Question 86 on the safety of use enzyme additives listed in notice 96/263 (O.J. N° C263, 11.9.96, p.3) following Article 5 of Council Directive 93/113/EC (O.J. N° L334, 31.12.93, p.17)

The draft report was discussed and it was agreed to change the Annex from a list of enzymes under consideration to a list of enzymes found to meet the scientific criteria. It was recalled that the examination of dossiers relating to other enzymes is continuing. It was furthermore decided to remove the chapter concerning general recommendations to the Commission from the draft report and to incorporate it in the minutes of the meeting. The latter recommendations are attached in Annex II.

The draft opinion, as amended in the plenary, was adopted by unanimity.

8.4) Question 85 on the safety of use the micro-organism additives listed in notice 96/263 (O.J. N° C263, 11.9.96, p.3) following Article 5 of Council Directive 93/113/EC (O.J. N° L334, 31.12.93, p.17)

SCAN discussed the revision of a working document that had been consolidated in November last year. The Committee recognised the importance of an equal treatment for all products and stressed that questions put by SCAN need to be answered properly by the companies. As for the previous issue it was recalled that the report should not be considered as a final one but that examination of dossiers relating to other micro-organisms enzymes is continuing.

The draft opinion, as amended in the plenary, was adopted by unanimity.

9. DISCUSSION OF PROGRESS REPORTS CONCERNING:

9.1) Question 70 on the use of formaldehyde as preservative-agent for feed

Discussion postponed

9.2) Question 89 on the use of diclazuril as feed additive for to rabbits

Discussion postponed

9.3) Question 93 on the Danish safeguard clause concerning the ban of virginiamycin in animal feed (urgent question)

Discussion postponed. The working group will meet again on 8 July.

9.4) Swedish request for a general ban on antibiotics, coccidiostats and other medicinal substances and growth promoters as feed additives

Discussion postponed

9.5) Request from Denmark to review the question of tylosin as feed additive

Discussion postponed

9.6) Question 63 on the use of virginiamycin in the feedingstuffs for sows and gilts (urgent question, opinion needed before June 1998)

Discussion postponed

9.7) Question 95 concerning the use of narasin as antibiotic feed additive in feed for pigs

Discussion postponed

10. OTHER POINTS

It was decide to transform the next plenary that was originally scheduled for 10 July into a two day meeting on 9-10 July. The working group meeting on enzymes foreseen for 9 July will be organised on 8 July (pm)

Annex I: Attendance

Members:

Dr. Georges BORIES
Prof. Arturo ANADÓN
Dr. Louis Aimé AUMAITRE
Dr. Joaquim BRUFAU
Dr. Andrew CHESSON
Prof. Tito H. FERNANDES
Dr. Anders FRANKLIN
Prof. Dr. Jürgen GROPP
Prof. Jean-François GUILLOT
Prof. A. V. KOVATSIS
Prof. Dr. Josef LEIBETSEDER
Prof. Gianfranco PIVA
Prof. David Michael PUGH
Dr. Atte VON WRIGHT (4 June)
Dr. Pieter WESTER.

Apologies for absence:

Dr. Niels AGERGAARD
Prof. Dr. Carlo BERETTA
Prof. Gerhard FLACHOWSKY
Dr. Atte VON WRIGHT (5 June)

Absent:

None

For the Commission:

DGXXIV:

Mr. J. Moynagh
Mr. R. Vanhoorde
Mr. B. Verleysen
Mrs. A Duysens

DGVI

Mrs D. André
Mrs I. Demade

Annex II

General recommendations to the Commission regard to Question 86 on the safety of use enzyme additives listed in notice 96/263 (O.J. N° C263, 11.9.96, p.3) following Article 5 of Council Directive 93/113/EC (O.J. N° L334, 31.12.93, p.17).

These comments apply to technical information that applicant firms should provide to enable correct assessment of their dossiers by the Committee. They primarily concern Section II (identity, characterisation, conditions of use, methods of control) Section III (efficacy) and Section IV (safety of use of the additive).

Section II: Whenever possible, enzymatic activities should be expressed in international units. Companies are requested to develop harmonised methods aimed at measuring active products directly in enzyme preparations and in feeds in order to comply with point 5.2 of section II of Commission Directive 94/40/EC.

In order to understand the function of the enzyme under physiological conditions of digestive tract of target species, the range of relevant properties (i.e. pH and temperature profiles) should be available.

For practical use, stability during the storage and/or feed processing (i.e. pelleting) should be determined. The data on stability at room temperature (25° C) is not sufficient, unless in the absence of additional data the indication "storage temperature should not exceed 25° C" is mentioned on the label. The effect of water activity on the stability of active substances in premixes and feeds should be evaluated.

The Committee is concerned with the incompatibility of mixing proteases with other enzyme preparations unless proved that efficacy is maintained.

Section III: It should be stressed that most files concerned with nutritional claims do not entirely fulfil the requirements of Annex III, point 2 § 1 of Commission Directive 87/153/EEC on the effects of additives on animal production, stating that dose-response relationship studies should be performed on each target species in comparison with negative control groups. Moreover, if the active substance is a mixture of active components, the presence of each component must be justified.

It would be advisable that the experimental work aimed to determine the efficacy should be, at least in part carried out at

an independent institution.

Section IV: Tolerance tests, the objective of which is to evaluate target animal safety in case of overdosing, must be conducted according to GLP or by methods providing equivalent guarantees.