EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C3 - Management of scientific committees II; scientific co-operation and networks

SUMMARY RECORD OF THE 134RTH SCAN PLENARY MEETING (BRUSSELS, 24-25 JANUARY 2001)

(APPROVED ON 21-22 MARCH 2001)

1. WELCOME, APOLOGIES

Three members sent apologies for absence. The list of those present is annexed.

2. DECLARATION OF INTERESTS

Ing. A. Aumaître declared that due to work carried out by INRA on Formi™ LHS, he would not participate to the discussion on question 108.

Prof. J.F. Guillot recalled his previous declaration on question 95 due to some work he carried out for the Company and therefore will not take part to discussion on it.

3. APPROVAL OF THE AGENDA

The agenda was presented by the Secretariat. It included some additions under Miscellaneous. Questions 097 and 110 were added as well as an information point relating to the rules of procedure adopted by the Committee in December 2000. The Committee approved the agenda as amended.

4. ADOPTION OF THE SUMMARY RECORD OF THE 133RD MEETING OF SCAN

The minutes of the previous SCAN meeting were adopted unanimously.

5. DISCUSSION AND POSSIBLE ADOPTION OF A SCIENTIFIC OPINION

5.1. Question 79 on the use of semduramicin in feedingstuffs for chickens for fattening

In the absence of any reply to the questions sent by SCAN at the end of October 2000, the draft report could not be finalised. Therefore the Committee did not discuss this question further.

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5.2. Question 108 on the use of potassium diformate in feedingstuffs for piglets and pigs for fattening (Formi™ LHS)

The rapporteur presented a draft report taking into account the comments made at the last plenary and reviewed in the light of the last claim made by the Company in its supplementary dossier submitted in November 2000.

The Committee discussed the document thoroughly and concluded that, on the basis of the last levels of incorporation of the product in the feed recommended by the Company, information was insufficient to conclude on the product Formi™ LHS. Additional data should be provided to conclude both on safety and on efficacy.

5.3. Question 96 on the use of a co-product of penicillin production as a source of protein for ruminants and pigs (Vevocel®)

Two members of the Committee were asked to review the document prepared by the rapporteur in order to finalise it.

5.4. Question 85 on the safety of use of 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)

The rapporteur presented the evaluation of the extension of use of product Biosaf SC47 to dairy cows. The tolerance test provided in the dossier was discussed by the Committee which concluded that its duration (two weeks) was insufficient for interpretation in adult ruminants. As a consequence, the Company will be asked to carry out a new tolerance test.

Product Pronifer MSB, made of several micro-organisms, was discussed. Two major strains of the product are resistant to tetracyclines, major antibiotics used in human and veterinary medicine. The Committee concluded that this would represent a risk and adopted accordingly a modification of its report on the use of certain micro-organisms as additives in feedingstuffs. A report dedicated to the product was also adopted unanimously.

This led the Committee to discuss the importance of the resistance to antibiotics, present in micro-organisms involved in the products submitted for assessment, in the conclusion drawn by the Committee on the risks related to their use in animal nutrition.

In the light of the Scientific Steering Committee opinion on antimicrobial resistance and on the basis of the experience gained through the numerous evaluations done by SCAN, the Committee considered necessary to publish the rules it follows for the assessment of micro-organisms. The Secretariat's attention was therefore drawn on this aspect.

Mandate could be given by the Commission to SCAN so that the Committee would issue an opinion, as in the case of the Bacillus toxins, identifying the practical requirements applicable to micro-organisms safety with regard to resistance to antibiotics, this in the light of the SSC opinion on antimicrobial resistance of 28 May 1999.

With regard to Bacillus toxin production aspect, the rapporteur presented the outcome of the evaluation of two products: Toyocerin® and Paciflor®. From the studies carried out, it appears that the dossier presented by the Company owning Toyocerin® is satisfactory with data obtained from independent laboratories and following the rationale recommended in the SCAN opinion on Bacillus. The strain involved in Toyocerin® is not able to produce toxins.

In the case of the dossier presented by the Company owning Paciflor®, studies were carried out within the company's laboratory. Data submitted demonstrate clearly that the strain involved is a toxin producer. Although a draft report on product Paciflor® could not be prepared for that SCAN meeting, the Working Group considered necessary to raise this issue immediately to the Committee and to the Commission, because of the safety implications of the toxin production. A draft report is intended for adoption for the March plenary.

In addition, the rapporteur brought to the Committee's attention that Company owning Paciflor® tested the competitor products for toxin production and brought conflicting information on the absence of toxin production in the other products. As a principle, SCAN takes the position that data which are not provided by the owner of the product or which are not published in the scientific literature, are not considered in its assessment.

5.5. Question 86 on the safety of use of 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 rapporteur presented the outcome of the assessment of several enzymatic products: extension of use of Roxazyme G2 liquid to turkeys, new form for this product called Roxazyme G2 granular intended for broilers and turkeys, extension of use of product Belfeed to piglets (up to 2 months of age).

The results are satisfactory and were accepted by the Committee, which adopted unanimously an update of its report on use of certain enzymes in animal feedingstuffs.

The discussion of product Belfeed led the Committee to reflect on the safety of the Bacillus strains used to produce enzymatic products. In the light of its previous opinion on the safety of use of Bacillus species in animal nutrition of 17 February 2000, the Committee agreed that a letter should be sent for all products already assessed (and involving a Bacillus strain) to their owners (through the Member State rapporteur) in order to obtain information regarding the toxin production. The text of the letter was agreed upon and the Secretariat is in charge of sending it to the Member States concerned.

6. PROGRESS REPORTS

6.1. Question 95 on the use of narasin as antibiotic feed additive in feed for pigs

Not discussed.

6.2. Question 106 on the use of canthaxanthin in feedingstuffs for laying hens, other poultry, salmon and trout

The group continues its work. A new meeting is scheduled for middle February.

6.3. Question 107 on the use of nifursol in feedingstuffs for turkeys

The rapporteur works with the members of the group on the question.

6.4. Question 111 on the use of *Bacillus licheniformis* NCTC 13123 in feedingstuffs for pigs (Product Al Care ®)

A question on resistance to antibiotics has been raised at an early stage of the evaluation in July last year. Answer has been received recently and the group addressed it in its meeting immediately before the plenary meeting. Additional information is needed on the resistance of the product to antibiotics. It has been requested from the Company. In addition, as this evaluation is done in accordance with the last amendment of the Council Directive 70/524/EEC, which includes a clock running, the group sent at the same time a number of other requests for further data.

6.5. Question 112 on the use of sodium benzoate, propionic acid and sodium propionate in feedingstuffs for pigs, cattle for fattening and dairy cows

Answers to questions have been received. The group should meet in February to discuss a draft report.

6.6. Question 113 on the use of astaxanthin-rich *Phaffia rhodozyma* in feedingstuffs for salmon and trout

The group continues its work.

6.7. Question 114 on the use of titanium dioxyde-coated mica in feedingstuffs for salmon and trout

The group continues its work. A question has been raised to the Company

6.8. Question 115 on the use of benzoic acid in feedingstuffs for pigs for fattening

The work is well advanced and the group will meet in February to discuss a draft report.

6.9. Question 116 on the use of manganomanganic oxide in feedingstuffs

Questions have been sent. The group will meet once answers will be available.

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

The Chairman presented the current activities of the Scientific Steering Committee, and asked in particular for members to join some of the SSC working groups.

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

Members participating to the GMO Working Group and to the TSE Working Group introduced shortly their activities.

9. NEW QUESTIONS

- A question on trace elements covering copper (Question 099) and zinc (Question 117) was submitted to the Committee. The Committee agreed to create a permanent working group in charge of such question, involving external expertise, which would ensure an harmonious evaluation of the different substances. Members have to be identified, including in the field of environment impact. In addition, as far as the specific questions 099 and 117 are concerned, members of two ad hoc working groups have to be identified. Names will be communicated by SCAN members.

- A question (Question 118) on efficacy and safety of a blend of lysine and tryptophane was addressed by the Commission, in accordance with Council Directive 82/471/EEC. Members of the group were identified. As the product results from a fermentation of a genetically modified organism, it was agreed that the "Genetic Modification" aspect would be addressed in the inter Committee GMO Working Group.

- The Secretariat informed the Committee that in accordance with Council Directive 70/524/EEC and the re-evaluation of certain additives it foresees, a number of dossiers of coccidiostats would be submitted in the near future, with a deadline for evaluation fixed to September 2003.

10. MISCELLANEOUS

None

Annex: Attendance

Members:

Prof. Arturo ANADÓN
Ing. Louis Aimé AUMAITRE
Prof. Dr. Carlo BERETTA
Ing. Georges BORIES
Dr Joaquim BRUFAU
Prof. Maria de los Angeles CALVO TORRAS
Dr Andrew CHESSON
Prof. Gerhard FLACHOWSKY
Prof. Dr Jürgen GROPP
Prof. Jean-François GUILLOT
Dr Ingrid Halle
Prof. Josef LEIBETSEDER
Prof. Gianfranco PIVA (second day)
Mr Derek RENSHAW
Mr Kristen SEJRSEN
Dr Pieter WESTER
Dr Atte VON WRIGHT

Apologies:

Prof. Diana ANDERSON
Dr Anne-Katrine Lundebye HALDORSEN
Prof. Gianfranco PIVA (first day)

For the Commission:

DG Health and Consumer Protection:

Mr E. Thévenard (Management of the scientific committees II)
Mr A. Verleysen (Management of the scientific committees II)
Mrs M. Duboile (Management of the scientific committees II)
Mrs I. Demade (Animal nutrition)
Mrs M. Lahrssen (Animal nutrition)