



EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions

C2 - Management of scientific committees; scientific co-operation and networks

**SUMMARY RECORD OF THE 137TH SCAN PLENARY MEETING
(BRUSSELS, 03-04 JULY 2001)**

(APPROVED ON 12 SEPTEMBER 2001)

1. WELCOME, APOLOGIES

The list of those present is annexed.

Professor Gianfranco Piva who resigned from the Committee, was thanked by the Chairman. A letter will be sent to him.

2. DECLARATION OF INTERESTS

No declaration of interests were made by the members attending the meeting.

3. APPROVAL OF THE AGENDA

The agenda was presented by the Secretariat. Item 5.2 was deleted and item 9.7 was moved to part 5.

4. ADOPTION OF THE SUMMARY RECORD OF THE 136TH MEETING OF SCAN

The minutes of the previous SCAN meeting were adopted unanimously. The adopted minutes of the 135th were distributed to the Committee.

5. DISCUSSION AND POSSIBLE ADOPTION OF A SCIENTIFIC OPINION

5.1. Question 120 on the criteria for assessing the safety of micro-organisms resistant to antibiotics of human clinical and veterinary importance

The Chairman of the group presented briefly the document to the Committee. The Committee considered the document thoroughly and agreed unanimously to the adoption of that opinion. The acknowledgement of the experts of the Working Group will be inserted in the opinion.

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

The Chairman of the group, who also acts as rapporteur, presented a draft opinion to the Committee. The document was extensively discussed by the Committee which invited the rapporteur to review and modify some parts of

the document. A Working Group meeting will therefore be organised in order to address SCAN comments and to present a draft amended accordingly.

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

The rapporteur introduced the draft report prepared by the Working Group. A few comments were expressed, and written submission of comments by SCAN members were asked by the rapporteur.

The particular problem of lead contamination of the product was raised. This is not surprising as it seems that manganese is commonly found and contaminated with lead. This applies to the product under examination and could also be the case for other manganic products already authorised by the Commission.

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

The rapporteur presented his draft report to the Committee. He drew the attention on the limitation of this exercise because of the absence of raw data, which would be necessary for a correct evaluation.

The Committee commented and asked for modifications of some parts of the text. The rapporteur will prepare a revised version in the light of these comments and with the help of working group members. The revised version could be circulated to the Committee for an adoption using the Written Procedure.

6. FEED-BACK BY THE CHAIRMAN ON SUBJECTS DISCUSSED IN THE SCIENTIFIC STEERING COMMITTEE (SSC) AND HAVING AN INTEREST FOR THE SCAN

None.

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

The SCAN member of the current SSC working group on Harmonisation of Risk Assessment informed the Committee of the progress made and presented a new draft.

8. NEW QUESTIONS

The Committee discussed the new mandates given by the Commission.

8.1. Question 128 on product Toyocerin ® for use as feed additive

The Commission requests the SCAN to consider the data on toxin production by Toyocerin®, presented in the dossier of a competitor product.

The Committee reiterated its reluctance to consider data not published in the scientific literature or not originating from the dossier submitted by the applicant, but finally will consider the data.

In the case where this would lead to different conclusions than those based on the dossier of the applicant ASAHI, SCAN would require a third study to decide on the safety.

A rapporteur is chosen.

The Secretariat highlighted that, apart from this toxin aspect, the questions on resistance to Tetracycline raised early this year have not been answered by the Company.

- 8.2. Question 129 on the safety of the enzymatic product Quatrzyme HP[®] for use as feed additive in laying hens

The Company asks for an extension of use of its product to a new animal category. The product has been assessed by SCAN for chickens for fattening and should now be considered for use in laying hens. The rapporteur is identified and some SCAN members will also participate to the evaluation. The Secretariat invites for identification of external scientific experts who could join the working group and help in the evaluation work.

- 8.3. Question 130 on the safety of the micro-organism product Provita E[®] for use as feed additive

The strain involved in that product has already been considered in the assessment of a competitor product. The question covers safety assessment of that product. The Working Group in charge of the safety of micro-organisms will do the evaluation. A rapporteur is identified.

- 8.4. Question 131 on the safety of the enzymatic product Belfeed B1100 ML[®] for use as feed additive for chickens for fattening

Product Belfeed B1100 ML[®] has already been assessed by SCAN. The product submitted now through Belgium (Member State rapporteur) is presented in a liquid form and intended for chickens for fattening. A rapporteur is chosen and two other scientists join for the assessment.

- 8.5. Question 132 on the safety of the enzymatic product Roxazyme G2[®] for use as feed additive in laying hens and piglets

This product has already been assessed by SCAN. The question covers an extension of use to two new target animal categories. A rapporteur was identified and two members of the SCAN will participate to the assessment. The Member State rapporteur is Belgium.

- 8.6. Question 108 on potassium diformate.

Following SCAN report on the product Formi[™] LHS, the Company provided a supplementary dossier in order to address SCAN conclusions on the product. In addition, the Company asks for an extension of use of its product to other categories.

SCAN will consider the information submitted. A new rapporteur is nominated for that product. He will be helped for some aspects of the evaluation by an other SCAN member.

In order to avoid the situation that occurred with the first evaluation of that product (see Minutes of the SCAN plenary of 21-22 March 2001, item 5.2), the rapporteur asks that the documents which should be considered by the SCAN, be well-identified. In addition, the Secretariat is asked to establish a new mandate for that product.

9. PROGRESS REPORTS

- 9.1. 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 can still not be finalised. Therefore the Committee did not discuss this question further.

- 9.2. 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)

One product remains on the agenda: Lisovit E. The group should finalise the assessment so that the question can be closed.

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

No progress on that question. The same product is to be evaluated under question 122 in accordance with article 9G of the Directive 70/524. Clarification from the Commission is awaited.

- 9.4. Question 99 on the use of copper in feedingstuffs

The Working Group is now completed and should start working.

- 9.5. Question 103-104 on the revision of the guidelines for micro-organisms and enzymes

The Working Group is well advanced in the drafting. An extraordinary plenary will be organised in September, dedicated to this question in order to discuss the text prepared by the Group.

- 9.6. Question 105 on the safety of Kalium- and Sodium ferrocyanid

The dossier is incomplete with regard to guidelines requirements and the information provided is rather old. Both products have been assessed by the SCF and are approved as food additives. The group will come with a proposed opinion to the SCAN in the near future.

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

No progress was made on this question. The clock stopped when questions were sent. Answers are awaited.

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

The rapporteur is finalising a report to be submitted to the Committee.

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

Not discussed.

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

No progress on this question. The additional dossier requested for a new member in the group has still not been provided.

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

Questions have been sent to the Company and results are awaited.

- 9.12. Question 117 on the use of zinc in feedingstuffs

No progress.

- 9.13. Question 118 on the use of a blend of L-Lysine-HCl (70%°) with L-Tryptophan (15-20%) and its residues of fermentation with *Escherichia coli* K-12 for piglets, pigs for fattening and chickens for fattening

No progress.

- 9.14. Question 119 on the use of formaldehyde as a preserving agent for animal feedingstuffs of 11 June 1999

Questions have been sent to the Company. Answers are awaited.

- 9.15. Question 121 on undesirable substances in feed

A first meeting should be organised for the horizontal group for September.

- 9.16. Question 122 on the reevaluation of coccidiostats and other medicinal substances in accordance with article 9G of Council Directive 70/524/EEC.

Groups are created. Dossiers are awaited.

- 9.17. Question 123 on 3-phytase EC 3.2.1.8 produced by *Aspergillus niger* CBS 491.94

Not discussed

- 9.18. Question 125 on the evaluation of the safety of Calfmix®, a micro-organism product

The product is under consideration. Questions should be sent to the Company.

9.19. Question 126 on the safety of the use of product Oralin[®] in turkeys

This is an extension of use of a product already authorised. Parts of the dossier are in German which slows down the evaluation process. German speaking experts will help. The question of language of submission of dossiers should be clarified.

9.20. Question 127 on the safety of product Emulbesto

The group starts working.

10. MISCELLANEOUS

Annex - Attendance

Members:

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

Apologies:

Prof. Arturo ANADÓN (second day)
Prof. Dr. Carlo BERETTA (second day)
Dr Andrew CHESSON (second day)

For the Commission:

DG Health and Consumer Protection:

Mr E. Thévenard (Management of SCAN)
Mr A. Verleysen (Management of SCAN)
Mrs M. Duboile (Management of SCAN)
Mrs M. Lahrssen (Animal nutrition legislation)
Mr C. Pampaloni (Animal nutrition legislation)