



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 135TH SCAN PLENARY MEETING (BRUSSELS, 21-22 MARCH 2001)

(APPROVED ON 16-17 MAY 2001)

1. WELCOME, APOLOGIES

The list of those present is annexed. The Chairman being delayed, the meeting started under the chair of the first SCAN Vice-Chairman.

2. DECLARATION OF INTERESTS

No declaration of interests.

3. APPROVAL OF THE AGENDA

The agenda was presented by the Secretariat. It included some additions under Miscellaneous, mainly provision of some documents for information of the Committee.

4. ADOPTION OF THE SUMMARY RECORD OF THE 134^{RTH} MEETING OF SCAN

The minutes of the previous SCAN meeting were discussed, amended accordingly and 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.

5.2. Question 108 on the use of potassium diformate in feedingstuffs for piglets and pigs for fattening (FormiTM 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. New information submitted by the Company immediately before

the plenary was not considered due to limited time given to Committee members.

A propos this situation, Professor G. Flachowsky, Professor J. Gropp and Professor J. Leibetseder, opposed strongly to the fact that dossiers submitted immediately before the SCAN plenary meeting be taken into account in the SCAN report, as the SCAN members are not given due time to consider the new data submitted. As a principle they consider that evaluation and discussion in the Committee should be stopped until all the relevant and necessary data for a proper evaluation are submitted in a well-established dossier and not piece by piece on a monthly basis.

The Committee discussed the draft thoroughly and concluded on the basis of the data available (with the exception of those submitted immediately before the plenary) that the efficacy and the safety were demonstrated only in some cases and for some animal categories. For the other cases of the claim, additional information would be needed to draw conclusions. The Committee adopted accordingly unanimously a report on the product FormiTMLHS®.

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

The rapporteur presented an amended draft report. The Committee discussed the document in detail and requested numerous modifications. The rapporteur will submit an amended version for a possible adoption at the next meeting.

- 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 assessment of product Paciflor® for toxin production was presented. The Committee agreed with the conclusions that the strain involved is a toxin producer and adopted unanimously the addition of that product in annex to the report on the use of certain micro-organisms as additives in feedingstuffs under the heading of product that pose a risk to human or animal health or to the environment.

For product Toyocerin®, although the toxin production was clarified by the data submitted by the Company, a safety aspect remains, for which information has been requested to the Company. Until submission of data, the product is removed from the annex to the report on the use of certain micro-organisms as additives in feedingstuffs.

The extension of use of Biosaf SC47® to dairy cows was also discussed. A new tolerance test had been requested at the last plenary meeting. Surprisingly, the Company had already carried out such a study but had not considered necessary to provide it earlier to the Committee. The results of this new study are satisfactory and led the Committee to adopt unanimously the addition of dairy cattle as target species for this product in annex to the report on the use of certain micro-organisms as additives in feedingstuffs.

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

A group on resistance to antibiotics, created by the SSC, will meet on 28 March to consider data on resistance submitted by the industry.

The SSC is currently discussing the question of mycotoxins, which will be addressed as well by SCAN under a new question on undesirable substances in feed.

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

Information was provided on the current SSC working group on Harmonisation of Risk Assessment. A document was distributed and SCAN members were invited to comment. Comments could be discussed shortly at the next SCAN meeting.

Update on the work of the GMO working group was also provided to the Committee.

8. NEW QUESTIONS

The Committee discussed the new mandates given by the Commission.

- A question (Q 105) covers the safety assessment of two anticaking agents (Potassium- and Sodium ferrocyanid). Members of the group were chosen by the Committee
- A question on trace elements covering copper (Q 099) and zinc (Q 117) was submitted to the Committee at the last plenary. The Committee discussed the composition of a permanent working group in charge of horizontal co-ordination of questions relating to trace elements. This permanent working group (Q 121a) will be chaired by a SCAN member and includes SCAN members as well as external experts, including SCTEE members.

As far as vertical working groups are concerned, experts will be contacted to join groups 099 and 117, respectively chaired by a SCAN member present in the above mentioned Working Group 121a.

- A review of data submitted by Company Anitox in reply to SCAN opinion of June 1999 on formaldehyde (Q 119) is asked by the Commission. Members of the group have been identified.

- A reactivation of question 103 & 104 on the revision of the guidelines for micro-organisms and enzymes. The group includes members already involved in the assessment of these categories of additives. The Committee endorsed that composition.
- In connection with Q 085, a new question (Q 120) relating to the safety of micro-organisms with regard to their resistance to antibiotics, in the light of the SSC opinion on antimicrobial resistance was addressed to the Committee, following the discussion of the January plenary. The group includes SCAN and external specialised expertise. The Committee endorsed its composition.
- A general question is raised on undesirable substances (Q 121) in the framework of the revision of Council Directive 1999/29/EC. Considering its wide scope, the Committee considered necessary to split the work among four specific vertical groups. Two members of each group will constitute an horizontal group in charge of coordinating and harmonising the work of each vertical group. The horizontal group (Q 121) was established. The vertical groups will cover the four following subjects, in relation to question 121:
 - Q 121a: heavy metals. This group is also in charge of trace elements.
 - Q 121b: products of micro-organisms (including mycotoxins)
 - Q 121c: organic contaminants
 - Q 121d: botanic impurities and vegetal substances

Their members have to be identified.

9. PROGRESS REPORTS

- 9.1. 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 agenda of this group is almost cleared. Only product Lisovit E® remains and the rapporteur is currently preparing a document for discussion in the Committee plenary.

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

No progress on this question.

- 9.3. 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 immediately after the plenary.

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

The group met in March. Data submitted by the Company are extremely limited and are made of reports or summaries. Raw data would be necessary to draw conclusions. Members and Secretariat will try to find such raw data. If not available, the group would have difficulties to give strong supported answers to Commission's questions on toxicity of the molecule.

- 9.5. 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.

- 9.6. 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 drafting a report to be submitted to the Committee.

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

The group continues its work. A new meeting is scheduled immediately after the plenary.

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

No progress on this question.

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

The group continues its work.

- 9.10. Question 116 on the use of manganomanganic oxide in feedingstuffs

The group received answers to the questions raised. A draft report could be proposed at the next plenary meeting for discussion.

10. MISCELLANEOUS

Some documents were distributed to the Committee, in relation to current or past items of the agenda:

- A critical review on Copper, which could be considered in the framework of Question 099
- FEFANA comments on the opinion on efficacy of enzymes
- The existing Council Directive 1999/29/EC, in connection with new question 121
- Comments from Prof. Ellar, submitted by United Kingdom, in relation to the SCAN opinion on Bacillus toxins issued in 2000
- An SSC document relating to Harmonisation of Risk Assessment.

Annex - Attendance

Members:

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

Apologies:

Prof. Maria de los Angeles CALVO TORRAS (second day)

For the Commission:

DG Health and Consumer Protection:

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