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 141RST SCAN PLENARY MEETING (BRUSSELS, 05-06 FEBRUARY 2002)

(APPROVED ON 17-18 APRIL 2002)

1. WELCOME, APOLOGIES

The list of those present is annexed.

The Chairman welcomed the Committee and presented his best wishes for the new year. The Secretariat informed the Committee of the recent publication of the regulation creating the European Food Safety Authority. It is likely that the current mandate of the Committee will be terminated earlier than foreseen as the set up of the new scientific panels of the EFSA could be expected for the end of the year.

2. DECLARATION OF INTERESTS

None for the meeting. The annual declarations of interests were all collected.

3. APPROVAL OF THE AGENDA

The agenda was approved with the reorganisation of the items under discussion for possible adoption, in particular with the addition of questions 106, 113 and 086.

Comments made on SCAN opinion were added under Miscellaneous for discussion with the Committee.

4. ADOPTION OF THE SUMMARY RECORD OF THE 139TH MEETING OF SCAN

The minutes of the 140th SCAN meeting were adopted unanimously. The adopted minutes of the 139th meeting were distributed to the Committee.

5. DISCUSSION AND POSSIBLE ADOPTION OF A SCIENTIFIC OPINION

5.1. Question 079 on Semduramicin

The question raised in January 2000 was answered by the Company in November 2001. The supplementary dossier provided was considered and the draft report, discussed by the Committee two years ago, amended accordingly. The rapporteur presented to the Committee the modifications made to the document. The Committee agreed to the modifications proposed. Due to the renewal of the Committee in 2000, some members raised other questions on

the rest of the document. Clarifications will be brought by the rapporteur before the document can be adopted. As this implies going back to the dossier which was left aside for two years, the product will be rediscussed at the next plenary.

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

The Committee had almost agreed to the adoption of the document at the last plenary although some amendments had to be made. As a Written Procedure could not be launched, the document as amended was presented by the rapporteur. The Committee supported the changes made and adopted unanimously the opinion.

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

The Committee dedicated most of that meeting to this question. Although the discussion focused on the parts relating to the assessment of the safety of canthaxanthin, the Committee considered the whole document.

Significant modifications were requested and the document could not be adopted. It will be amended in the light of the discussion and will be resubmitted to the Committee for a possible adoption.

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

The document was amended on the basis of last meeting's comments. The amendments were presented, discussed and agreed upon. The document was approved unanimously with the provision that some additional modifications would be made before publication.

5.5. Question 86 on the safety of use of enzymes

One product remains on the agenda of this old question: Lisovit E®. The rapporteur finalised the assessment of the product but the conclusions could not be presented. This will be discussed at the next plenary meeting.

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

The Chairman informed the Committee of the possible organisation of a workshop on the subject of separation of risk assessment and risk management functions. He would welcome the representation of the Committee in this manifestation. The organisation of the workshop is for the time being at a very early stage and further precision will be brought when available.

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

SCAN members attending other working groups such as *Harmonisation of risk assessment* in the SSC or *Joint Working Group SCF/SCP/SCAN on Genetically Modified Organisms* briefed the Committee on their respective tasks and work.

8. NEW QUESTIONS

Numerous questions that had not been discussed in previous meetings were considered. Consequently, a number of new working groups were set up and rapporteurs identified.

8.1. Question 121 on undesirable substances

Group 121a on heavy metals is complete.

Group 121b on products of micro-organisms, including mycotoxins needs reinforcement with three possible experts, who will be contacted by the Secretariat.

Group 121c on organic contaminants is complete

Group 121d on botanical impurities needs additional expertise. None was identified.

8.2. Question 132 on safety of enzymatic product Roxazyme G2 for laying hens and piglets

The enzyme Working group will take care of that question. The rapporteur was identified.

8.3. Question 134 on safety of enzymatic product Allzyme PT for turkeys for fattening

The enzyme Working group will deal with that extension of use. The rapporteur was identified.

8.4. Question 135 on the review of the opinion on Formi LHS

The member of the group in charge of the first drafting who had been unofficially charged of reviewing the supplementary documents provided by the Company asked some help for this exercise. The group is therefore completed with two additional experts. The committee endorsed the rapporteur identified previously and agreed to the composition of the group. The question covers the safety problems identified in the SCAN opinion on the product and the stability of the liquid form of the product.

8.5. Question 136 on the efficacy of salinomycin sodium as coccidiostat in laying hens

In combination with the question 122 based on article 9G requirements, the efficacy of salinomycin sodium in laying hens will be checked. A rapporteur and a co-rapporteur have been identified.

8.6. Question 137 on the efficacy of micro-organism product Biosaf SC47 in cattle for fattening

The Working Group on the safety of micro-organisms will be reinforced with an additional nutritionist and will deal with that question, which covers only the efficacy aspect. A rapporteur and a co-rapporteur are identified.

8.7. Question 138 on safety of micro-organism product Turval BO399 for weaning piglets

The Working Group on the safety of micro-organisms is in charge. A rapporteur is identified.

8.8. Question 139 on the safety of enzymatic product Belfeed B1100 ML for pigs for fattening

The Working Group on the safety of enzymes is in charge. A rapporteur was identified. The Secretariat stressed the involvement of the microbiologists in the evaluation of the data submitted on the toxin production ability of the strains of Bacillus involved in the production.

8.9. Question 140 on the safety of enzymatic product Belfeed B1100 MP/ML for turkeys for fattening

The same group and rapporteur are in charge as for question 139

8.10. Question 141 on the safety of enzymatic product Biofeed phytase for sows

The Working Group on the safety of enzymes is in charge. A rapporteur was identified.

9. PROGRESS REPORTS

9.1. Question 85 on the safety of use of micro-organisms

There remain a few products on the agenda for which clarifications on the genetic basis of resistances to certain antibiotics are awaited.

9.2. Question 99 on the use of copper in feedingstuffs

The group continues its work and progressed significantly. A working group meeting is scheduled in March to discuss a draft opinion.

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

Answers to questions raised some time ago on the resistance of the strain involved in the product to erythromycin just arrived to the Secretariat and working group members. The Working Group will address them at the occasion of its next meeting in March

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

No progress on that question. The report should be finalised.

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

A member of the group is still lacking the dossier to start working. It has been requested several times. The Secretariat is asked to reiterate the request. In the absence of a satisfactory reaction, the SCAN will reject the question.

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

Several questions have been sent to the Company on product Vevovitall® (benzoic acid). The Company is now preparing answers and making relevant studies.

The Company contacted the Secretariat in order to clarify the need for the residue study requested by the Working Group. The rapporteur raised that request in order to obtain the position of the Committee.

The Committee was of the opinion that the toxicological profile of benzoic acid was adequately documented and that the residues left in food derived from treated animals were likely to be low in comparison with the ADI. The Committee noted a pharmacological study that the Company had highlighted as giving residues information. The protocol of the study was considered to be inadequate for the purpose of investigating residue depletion following recommended use of benzoic acid as a feed additive, but it was noted that the reported residues detected would take up only about 0.2% of the ADI if consumed. The Committee retained its option to request any further residues studies that it felt necessary following the discussion of the draft report on Vevovitall®.

9.7. Question 117 on the use of zinc in feedingstuffs

The group will meet in March.

9.8. 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

The rapporteur had prepared a draft on this question for a preliminary discussion in the Committee. For timing reasons, this could not be discussed.

9.9. Question 119 to update the opinion on the use of formaldehyde as a preserving agent for animal feedingstuffs

The company replied to the questions raised in 2001. The Working Group considered the answers provided in a meeting in January and raised some additional questions.

9.10. Question 121 on undesirable substances in feed

There is a need for additional expertise for some aspects of the question (see item 8.1)

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

The sub-groups are established. The tasks have been distributed and the dossiers (electronic and/or paper versions) have been received. Work can start. The Secretariat will organise the first meetings.

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

No progress on that question.

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

Questions have been sent to the Company in 2001. No further progress pending reply.

9.14. Question 126 on the safety of the use of product Oralin in turkeys

Questions have been sent to the company. The work is stopped until reply.

9.15. Question 127 on the safety of product Emulbesto

No progress on that question.

9.16. Question 129 on the safety of the enzymatic product Quatrazyme HP® for use as feed additive in laying hens

A question has been sent to the Company as the tolerance test was not carried out with ten times the maximum dose claimed in the feed.

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

Assessment will be discussed at the next meeting of the Working Group.

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

Work is progressing. It should be noted that information on the toxin aspect has been received. It will be considered with the microbiologists.

9.19. Question 133 on the efficacy of the coccidiostat « Cygro 1% ®» (maduramicin ammonium alpha) for use as feed additive

Erroneous question. Withdrawn by the Commission services.

10. MISCELLANEOUS

10.1. Comments on the SCAN opinion on BioProtein® of December 2001

The SCAN considered the letter sent on 17 January 2002 by the firm Dansk Bioprotein A.S. on the opinion on product BioProtein®. SCAN keeps its position on the adverse effects of the product in target animals and will not reopen the question unless officially requested by the Commission.

10.2. Comments on the SCAN opinion on Nifursol® of December 2001

The Company Solvay Pharmaceuticals (Vitamins & chemicals) owning Nifursol® informed SCAN in a letter that some histopathological data of 1970 were available on carcinogenicity. SCAN considered them. They confirm the conclusion on carcinogenicity reached in the opinion adopted in December 2001, which from provisional can now be considered definitive.

The concerns expressed by the Committee on that product remain however in particular its genotoxic potential and the absence of a kinetic study of residues. SCAN conclusion that safety of Nifursol® is not demonstrated remains.

10.3. Comments on the SCAN opinion on the criteria for assessing the safety of micro-organisms resistant to antibiotics of human clinical and veterinary importance

A letter from Roche Vitamine GmbH addressed to the Commission on the above SCAN opinion was forwarded to the Committee as comments were of a technical and scientific nature. Some of the comments are considered relevant and will be further discussed with the SCAN microbiologists. A final position could be ready for the next plenary meeting.

10.4. General remark

Considering its agenda, SCAN cannot dedicate any longer time to products where the assessment is completed and the opinion issued. Continuing time-consuming discussions because of continuous companies' letters on SCAN opinions are detrimental to the progress on other on-going evaluations. Data, if any, should have been submitted at the time of the assessment, in accordance with the guidelines. In the case of possible new scientific data, these should follow the legislative procedure and be subject to an official question from the European Commission. Unless officially required to address them, SCAN will not further discuss such correspondence.

Annex - Attendance

Members:

Prof. Arturo ANADÓN
Prof. Diana ANDERSON
Ing. Louis Aimé AUMAITRE
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
Dr Anne Katrine Lundebye HALDORSEN
Mr Derek RENSHAW
Mr Kristen SEJRSEN
Dr Pieter WESTER
Dr Atte VON WRIGHT

For the Commission:

DG Health and Consumer Protection:

Mrs M. Duboile (Management of SCAN)
Mr E. Thévenard (Management of SCAN)