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 142ND SCAN PLENARY MEETING (BRUSSELS, 17-18 APRIL 2002)

(APPROVED ON 18-19 JUNE 2002)

1. WELCOME, APOLOGIES

The list of those present is annexed.

2. DECLARATION OF INTERESTS

None for the meeting. Some declarations made at the occasion of previous meetings are still valid.

3. APPROVAL OF THE AGENDA

The agenda is approved after slight reorganisation.

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

The minutes of the 141rst SCAN meeting are adopted unanimously after inclusion of some modifications. The adopted minutes of the 140th meeting are distributed to the Committee.

5. DISCUSSION AND POSSIBLE ADOPTION OF A SCIENTIFIC OPINION

5.1. Question 079 on Semduramicin

The rapporteur addressed and answered the questions raised by the Committee at the last meeting and presented an updated version of the document. Some additional editorial comments were made and the document was adopted unanimously by the Committee. The report concludes to the safety of semduramicin for chickens for fattening, with a limited margin of safety, and to the efficacy of the product when used at 25 ppm. Efficacy at 20 ppm still needs further studies to be completely demonstrated.

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

An entirely revised version was presented to the Committee with a better focus on the terms of reference. It addressed in addition the concerns expressed at several occasions by the Committee. The draft opinion was again

considered thoroughly by the Committee, which agreed unanimously to its adoption, after inclusion of some amendments. SCAN concludes that, on the basis of the current levels of use of canthaxanthin in animal nutrition, the Acceptable Daily Intake fixed by the SCF in 1997 is exceeded and recommends action to ensure consumers' safety.

5.3. Question 86 on the safety of use of enzymes

Product Lisovit E® is the last enzymatic product on the agenda of SCAN submitted in accordance with Council Directives 93/113/EEC and 93/114/EEC. The rapporteur presented a summary of the assessment of the product and the conclusions of the working group. This product is different from the other enzymatic products assessed until now because of its claimed action on the microflora rather than on a feed material substrate. The Committee asked the rapporteur to review the summary assessment and did not agree to endorse the conclusions as presented.

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

The rapporteur presented the conclusions of the working group on product Al Care®. The concerns about the presence of antibiotic resistance genes led to conclude the review of the product before all safety-related issues had been fully resolved. The SCAN agreed with the conclusion that the use of the product as feed additive would be unsafe because of the risk to disseminate genes conferring resistance to antibiotics of human clinical and veterinary importance. It adopted unanimously the opinion.

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

The document presented by the rapporteur was not adopted. The repartition of animals in the tolerance test and the analysis of the quantities really administered to the animals were lacking. The Secretariat informed the Committee of the proximate submission of an other test by the company via the Member State rapporteur. Consequently, the document is sent back to the working group for update in the light of about-to-be submitted information and on the basis of the SCAN remarks.

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

The powder form of product Belfeed® has already been assessed and is authorised for this animal category. The company intends to market a liquid form as well. The working group concluded that the liquid form of the product, when used at the proposed level of inclusion in feed, is safe. The SCAN agreed unanimously and the report was adopted accordingly.

However, as two questions relating to toxin production have been sent to the company recently and are not yet answered, the adoption will only be valid under the condition that the awaited answers are brought by the company and are satisfactory.

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

The rapporteur presented the outcome of the evaluation. The Committee insisted on the need to follow the last adopted guidelines for enzymes and micro-organisms, in particular the requirements for the tolerance tests and could not agree to the adoption of the draft report. The group will review its draft in the light of the comments made and the clarification requested. It may have to go back to the company to address the SCAN concerns.

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

The rapporteur presented the favourable outcome of the evaluation. The data presented had been previously examined for piglets and SCAN had concluded that the product was well tolerated by piglets. In the view of the Committee, an additional study with older animals is unnecessary and the SCAN agreed unanimously to the adoption of the report.

However, as two questions relating to toxin production have been sent to the company recently and are not yet answered, the adoption will only be valid under the condition that the awaited answers are brought by the company and are satisfactory.

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

The product already assessed for chickens and for pigs was also considered for turkeys for fattening. The rapporteur presented the assessment and the Committee agreed unanimously to the conclusion reached by the working group. The report was therefore adopted.

However, as two questions relating to toxin production have been sent to the company recently and are not yet answered, the adoption will only be valid under the condition that the awaited answers are brought by the company and are satisfactory.

5.10. 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 presented a draft report to the Committee and highlighted the difficulties encountered in the evaluation of this blend of amino-acids. It was agreed that the report should be finalised on the basis of the data submitted by the company. The document could be finalised for the next time.

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

Not discussed.

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

Not discussed.

8. NEW QUESTIONS

8.1. Question 142 on the safety of fumaric acid

A question on the safety of fumaric acid for calves and more generally ruminants is submitted to the Committee following concerns raised by Germany in the Standing Committee on Animal Nutrition on the basis of a recent scientific publication. The Committee is asked to advise the Commission on the relevance and impact of this publication. Two SCAN members will be in charge.

8.2. Question 143 on coccidiostats Kokcisan 120G (salinomycin sodium) for chicken for fattening

This question joins the other questions relating to coccidiostatic substances (Q 122 and Q 136). The same experts will be in charge.

9. PROGRESS REPORTS

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

The Commission stopped the evaluation of Velab bovini, suini and Kluyten in the Standing Committee. This implies that evaluation by SCAN should be stopped as well. This will be clarified by the Secretariat.

9.2. Question 99 on the use of copper in feedingstuffs

Work progresses. The group meets immediately after the plenary and a draft opinion is prepared.

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

The draft is not yet finalised. It should be completed in order to allow a discussion for possible adoption at the next plenary meeting.

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

All members have received the dossier. The work is only at an early stage for the moment.

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

The company is doing some tests at the request of the SCAN. The working group already prepared a draft that just needs completion once replies are received.

9.6. Question 117 on the use of zinc in feedingstuffs

The work progresses. A draft opinion will be discussed at the next meeting of the group.

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

Questions have been raised to the company. A draft report is however ready and could be completed once answers are received.

9.8. Question 121 on undesirable substances in feed

All aspects are under consideration except for the botanical impurities where the lack of identified experts causes delays. Examination of the various substances listed in annex to Council Directive 1999/29/EC is taking place for heavy metals, mycotoxins and organic contaminants. Contribution on each of the listed substances, as well as on possible additional ones, is expected for the end of June.

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

All aspects of the evaluation of the products have been subject to discussions by the different working groups. It appears clear from the discussions that, as this is a re-evaluation, data submitted should be as recent as possible, although some flexibility can be accepted in some cases. In general, data post 1990ies would be required.

The Committee raised the aspect of the electronic submission of dossiers. Although CD-ROMs are convenient for handling, those provided by the companies have a very basic organisation, without any hyperlink, which makes the information difficult to find. Companies should be invited to improve the system and to help the experts to find the information, as, for the moment, this is extremely time-consuming for the evaluators.

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

Work is under progress. It appears that not all information was available in the last dossier submitted and some experts need to refer back to the old original submission for FTU 8. The Secretariat will take care of that.

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

No answer has been received from the company, therefore evaluation is suspended.

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

A letter has been sent to the company asking for some information and highlighting the difficulties for non german-speaking experts to assess the dossier submitted (almost all in german). A translation in english provided by the company would ease the evaluation.

9.13. Question 127 on the safety of product Emulbesto

Work is under progress. The company restricted its claim to calves and the rapporteur will review the document in the light of that modification.

The presence of animal fat in a product intended for ruminants was raised by the rapporteur and will be highlighted in the document, as this may be in conflict with the current legislation linked to bovine spongiform encephalopathy.

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

Questions have been sent to the company and evaluation is suspended until answers are received.

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

The group presented the outcome of the first discussions on the product. The Committee shares the concerns raised by the group on the unknown linked to the fermentation media used to dilute the active substance and agreed that this should be clarified. A question will be sent to the company covering in particular this aspect. In addition the tolerance test is not satisfactory and should be redone.

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

The work progresses and a draft report could be submitted to the plenary at the occasion of the next meeting.

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

This new question has not already been considered as the dossier is still awaited.

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

The dossier has been received and is now under examination.

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

The dossier has not arrived yet to the members of the group.

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

The dossier has not arrived yet to the members of the group.

10. MISCELLANEOUS

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

The Committee examined an additional residue study of 1967 submitted by the company. It is a global kinetic study carried out using C^{14}-labelled nifursol and based on the measurement of the whole radioactivity in the tissues. Although these results are worth considering and answer part of the requests of the SCAN, they do not satisfy all the requirements. According to the Guidelines a kinetic study of the depletion of unchanged nifursol and major metabolites (above 10%) in the edible tissues following nifursol withdrawal is mandatory in order to identify the target-tissue and marker-residue. The quantitation of metabolites and eventual identification for those representing more than 10% of the total residual radioactivity is a pre-requisite to that study.

As far as mutagenicity is concerned, the Committee looked at the proposal of the company to perform a standard *in vitro* TK gene mutation assay. Although SCAN recognises that there are no validated in vivo tests for mutagenicity other than bone marrow assays and the liver UDS assay, submission of an additional *in vitro* test would not allay the concerns raised by the positive results in some of the tests already submitted. In order to confirm the absence of *in vivo* mutagenicity already demonstrated in bone marrow, the SCAN reaffirms its request for a further suitable (*i.e.* not UDS) *in vivo* test in a tissue other than bone marrow. The *in vivo* test should be performed in accordance with Good Laboratory Practices and should be well described.

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

The Committee considered the letter sent by Dr H. Scherf and Dr A. Busch from Roche Vitamine GmbH and agreed to amend its opinion on the criteria for assessing the safety of micro-organisms resistant to antibiotics of human clinical and veterinary importance. The Minimum Inhibitory Concentrations of kanamycin/neomycin and streptomycin will be modified in table 4 of that opinion, for *Enterococcus faecium*. Both values will now be 1024.

Annex - Attendance

Members:

Prof. Arturo ANADÓN
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

Apologies:

Prof. Diana ANDERSON

For the Commission:

DG Health and Consumer Protection:

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