Minutes of the 122 nd meeting of the Scientific Committee on Food held on 6/7 September 2000 in Brussels

ATTENDANCE LIST - LISTE DES PARTICIPANTS - TEILNEHMERLISTE

Members/Membres/Mitglieder

Mme. S. BARLOW, MM. A. CARERE, D. BOSKOU, I. ELMADFA (2 nd Vice-Chairman, Vice-President, Stellv. Vorsitzender), Mme. A. FERRO-LUZZI, MM. A. FLYNN, R. FRIES, W. GRUNOW, Mme. A. KNAAP (1 st Vice-Chairman, Vice-President, Stellv. Vorsitzende), MM. I. KNUDSEN (Chairman, President, Vorsitzender), B. MOSELEY, K-H. NAU (present on 6 September only), A. PALOU, P. TOBBACK, P. Verger, J.-M. WAL, R. WALKER

Experts

Mr. J. ALEXANDER (item 8)

Apologies for absences:

S. LINDGREN, W. SARIS

Commission/Kommission

Mrs H. Hoffmann (DG Health & Consumer Protection), Mr. A. KLEPSCH (DG Health & Consumer Protection), Mr. K. MADSEN (DG Health & Consumer Protection), Mrs K. Neubauer (DG Health & Consumer Protection), Mr. L. ROSSI (DG Health & Consumer Protection), Mr. B. MATHIOUDAKIS (DG Health & Consumer Protection)

Secretariat/Secrétariat/Sekretariat (DG Health & Consumer Protection)

Mr M. A. GRANERO ROSELL, Mr D. PETTAUER, Mrs E. AGRO

1. Apologies for absence

The apologies for absence were noted.

2. Adoption of the agenda

The draft agenda was adopted.

3. Declarations of interest

There were no interests declared.

4. Adoption of the minutes of the 121 st meeting

The draft minutes of the previous plenary session, the 121 st meeting held on 20/21/22 June 2000 were examined and agreed after a number of minor changes were introduced.

5. Matters arising since last Plenary

5.1. Update of the opinion on crystalline beta carotene from Blakeslea trispora

The Committee had been made aware about a lack of clarity regarding the strains of *Blakeslea trispora* mentioned in the opinion on beta carotene produced from this microorganism in the opinion adopted by the Committee at the previous plenary session (SCF/CS/ADD/COL/158 Final). The Working Group on Microbiology and Hygiene had considered the matter and recommended to correct the opinion accordingly. The Committee agreed to this suggestion. The corrected opinion appears as Annex I to these minutes and replaces the text of the opinion as adopted at the previous plenary.

6. New requests of opinions

Consideration of a submission from the Italian Authorities raising concerns for the safety of certain products approved under the notification procedure of Regulation (EC) No 258/97 on novel foods and novel food ingredients

The Committee received an urgent request from the Commission regarding the evaluation of the scientific grounds provided by the Italian authorities when adopting national legislation suspending the marketing of certain novel foods and to invoke the safeguard clause laid down in the Regulation on Novel Foods.

7. Novel Foods

7.1 Draft opinion on a request to consider a submission from the Italian Authorities raising concerns for the safety of certain products approved under the notification procedure of Regulation (EC) 258/97 on novel foods and novel food ingredients

The Committee was asked whether information submitted by the Italian authorities provide grounds, detailed or otherwise, for considering that the use of the novel foods in question endangers public health. This question was brought to the Committee as a matter of urgency.

The documentation received by the Commission consisted of opinions issued by the Italian Health Council and the Italian Health Institute relating to potential health effects of certain genetically modified food products. These include products derived from four maize lines and three rapeseed lines which had been notified for placing on the market under the Novel Food Regulation. These products had been evaluated previously for their safety by the UK Advisory Committee on Novel Foods and Processes. The Committee noted that both these previous evaluations and the opinion of the Italian Health Institute concluded that these products were safe for human consumption. In its considerations the Committee needed to clarify whether it was required to perform a full safety evaluation of the products in question. It acknowledged that the mandate was restricted to the consideration of the scientific information submitted by the Italian authorities. After a detailed discussion the Committee adopted the opinion attached as Annex II to these minutes.

7.2 Draft opinion regarding a request in relation to the evaluation of toxicological information related to the safety assessment of genetically

modified tomatoes

The Committee had discussed this issue at the last plenary and had decided to refer the text drafted ad hoc to the Working Group on Novel Foods for revision. The new draft version was discussed and adopted after introduction of further amendments.

The full text of this opinion appears as Annex III to these minutes.

7.3 Draft opinion on bacterial dextrans

The rapporteur introduced the draft prepared by the Working Group on Novel Foods. During the discussion it became apparent that there were a number of issues that required further explanation and clarification, as well as a number of editorial and presentation changes.

It was decided to continue the discussion at the next meeting on the basis of a revised draft.

8. Upper levels for vitamins and minerals. Progress report

- 8.1. Discussion on an upper level for selenium
- 8.2. Discussion on an upper level for manganese
- 8.3. discussion on an upper level on beta carotene

The Committee examined the drafts prepared by the rapporteurs and discussed thoroughly by the Task Force. Members expressed satisfaction about the progress in this area. As regards the discussion on selenium it was decided that a number of sections should be made more clear, as well as the reasoning for deriving upper levels. In the case of the report on manganese there was an overall agreement on it subject to a number of small changes. As regards the paper on the upper level on beta carotene, the Committee decided to look first on the general paper on beta carotene from all dietary sources (see below). The draft on upper level for beta carotene required some further changes that were highlighted during the discussions.

As a conclusion, the Committee decided to reserve the adoption of all the papers on upper levels for the different nutrients that were sufficiently discussed at the level of the Task Force at the next meeting to ensure overall consistency and homogeneous approach and presentation among all the nutrients evaluated.

9. Beta carotene

Discussion on beta carotene from all dietary sources

The Committee had had at the previous meeting a thorough discussion on the issue already. Following the discussions the remaining issues had been addressed by the rapporteur at the different Working Groups. It was considered that the new draft reflected these points adequately. Following this discussion a number of changes were introduced and agreed.

The text of the full opinion appears as annex IV to these minutes.

10. Additives

10.1. Draft opinion on sucralose

As agreed at the previous plenary, the Committee was presented with a new draft that incorporated the evaluation of the latest studies submitted and the discussions at the plenary. The Committee was now satisfied with the overall evaluation of the safety in use of this substance requested as new sweetener, as laid down in the draft opinion. The full opinion appears as Annex V to these minutes.

11. Safety of creatine supplementation

The paper on the safety of creatine supplementation incorporating the changes discussed at Working Group level was discussed and agreed.

The full text of this opinion appears as annex VI to these minutes.

12. Contaminants: Progress report from the Task Force on dioxins

The Chair of the Task Force on Dioxins reported that good progress had been made in the Task Force. A final meeting was scheduled for 14/15 September and a draft opinion will be presented at the next plenary meeting.

13. Revision of schedule of SCF meetings

Schedule for 2000

The Committee discussed the consequences that the next plenary meeting might be the last meeting under the current mandate of its members. Taking into account the heavy workload of the Committee and the likely high number of matters of substantial content to be dealt with at this meeting, the members agreed to extend the duration of the next meeting to 3 days and a half (16 to 19 October).

The Secretariat informed the Committee that a possible first meeting of the new membership of the SCF had been provisionally scheduled for 21 and 22 November. The final schedule will depend on progress with the renewal procedure of the mandates of scientific committee members.

14. Work programme of the SCF

The Secretariat reported about the status of dossiers pending finalisation. The Committee noted that opinions on a large number of requests (approximately 125) are pending and that this situation was unlikely to change in the near future due to the limited capacity of the Committee. An informal exchange of views on possible ways of increasing the efficiency of the Committee followed.

15. General information from the Commission services

The Secretariat reported about the current status of the renewal process of the scientific committees and in particular the Scientific Steering Committee.

16. Progress reports from Working Groups

Due to the lack of time no detailed progress reports were made.

17. Any other business

17.1. Statement on D- - tocopheryl acid succinate (TAS)

The Committee evaluated a number of substances, including D- - tocopheryl acid succinate (TAS), intended to be used in the manufacture of foods for particular nutritional purposes (PARNUTS) in May 1999 (SCF/CS/ADD/NUT/20 final, opinion expressed on 12/5/99).

In the case of TAS, the Committee considered it temporarily acceptable, pending submission of additional information within one year of publication of the opinion to clarify the extent of hydrolysis of TAS in the gut and, consequently, whether any unhydrolysed TAS is available for absorption.

The Committee has received additional information but this was not sufficient to clarify the extent of hydrolysis of TAS. The Committee is therefore requesting further clarification on this issue from the petitioner.

In the meantime, in the light of the long history of use of TAS as a human medicine and studies in humans showing that tocopherol is bioavailable when TAS is ingested (though not the extent of bioavailability), the Committee agrees to extend its temporary acceptance of TAS for a further 2 years with the proviso that the requested information be submitted to the Committee within one year from now.

18. Adoption of these minutes

These minutes were adopted at the 123 rd Meeting of the SCF, held on 16-19 October 2000 in Brussels.

ANNEXES

(The text of the opinions adopted in these annexes appear in the section outcome/opinions of the webpages of the SCF on the Internet).

- ANNEX I Opinion on β-carotene from *Blakeslea trispora* (corrected) (SCF/CS/ADD/COL/158 correction)
- <u>ANNEX II</u> Opinion concerning a submission from the Italian authorities raising concerns for the safety of certain products approved under the notification procedure of Regulation (EC) 258/97. (CS/NF/DOS/11 ADD 4 REV 2 Final)
- ANNEX III Opinion on the evaluation of toxicological information related to the safety assessment of genetically modified tomatoes (CS/NF/TOM/8 ADD 1 REV 3 Final)
- <u>ANNEX IV</u> Opinion on the safety of use of beta carotene from all dietary sources (SCF/CS/ADD/COL/159 Final)
- ANNEX V Opinion on sucralose (SCF/CS/ADDS/EDUL/190 Final)
- ANNEX VI Opinion on safety aspects of creatine supplementation (SCF/CS/NUT/SPORT/9 Final)