Minutes of the 121 st Meeting of the Scientific Committee on Food held on 20/21/22 June 2000 in Brussels

ATTENDANCE LIST/LISTE DES PARTICIPANTS/TEILNEHMERLISTE

Members/Membres/Mitglieder

Mme. S. BARLOW, MM. A. CARERE (present on 21/22 June), D. BOSKOU, I. ELMADFA (2 nd Vice-Chairman, Vice-President, Stellv. Vorsitzender) (present on 21/22 June), Mme. A. FERRO-LUZZI, MM. A. FLYNN, R. FRIES (present on 21/22 June), W. GRUNOW, Mme. A. KNAAP (1 st Vice-Chairman, Vice-President, Stellv. Vorsitzende), MM. I. KNUDSEN (Chairman, President, Vorsitzender), S. LINDGREN, B. MOSELEY, K-H. NAU (present on 21/22 June), A. PALOU (present on 21/22 June), W. SARIS (present on 21/22 June), P. TOBBACK, (present on 21/22 June), P. Verger, J.-M. WAL, R. WALKER

Experts

Mr H van den BERG (item 13.2)

Commission/Kommission

Mr J.C. CAVITTE (DG Health & Consumer Protection), Mrs S. HEINIMAA (DG Health & Consumer Protection), Mrs H. Hoffmann (DG Health & Consumer Protection), Mr A. KLEPSCH (DG Health & Consumer Protection), Mrs K. Neubauer (DG Health & Consumer Protection), Mr L. ROSSI (DG Health & Consumer Protection), Mr F. VERSTRAETE (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

There were no absences.

2. Adoption of the agenda

The draft agenda was adopted.

3. Declarations of interest

There were no interests declared.

4. Matters arising from the minutes of the 120 th meeting

The minutes of the 120 th meeting which had been agreed before the meeting and published on the internet were noted.

5. Matters arising since last Plenary

The chairman reminded about the heavy workload of the Committee before the end of its mandate and the heavy agendas of the present and forthcoming meetings until the end of the mandate of the current membership of the Committee.

6. New requests of opinions

6.1. Request for modification of purity criteria of L-cysteine as food additive

The Committee was informed of a new request to examine the safety of L-cysteine produced by a particular fermentation process. The dossier will be looked at by the Working Groups on Additives and Novel Foods.

6.2. Reconsideration of the opinion on ethyl hydroxyethyl cellulose

The Committee is asked to reconsider the safety in use of ethyl hydroxyethyl cellulose as a food additive previously evaluated by the Committee on 24 March 1999 (CS/ADD/EMU/176 final) in the light of additional information, in particular regarding the potential presence of impurities such as ethylene oxide, 1, 4 dioxan, ethylene chlorohydrin, and mono- and diethylene glycol. This question has arisen during the interinstitutional legislative process of the Commission proposal regarding the modification of the existing directive on miscellaneous additives.

6.3. Food Consumption Factors used in food contact materials

The Committee is asked to consider whether surveys of fat intake recently submitted by a number of industry associations are adequate and whether using a figure for 200 grams of fat as a more realistic figure of fat intake instead of the current assumption of 1 kg fat could be applied in the risk assessment of food contact materials and if so, under which conditions.

Detailed final terms of reference for this question will be prepared by the Commission services.

6.4. Request for assessment of the genetically modified maize line "Roundup Ready GA21"

According to the procedure for market authorisation under Regulation (EC) N° 258/97 on novel foods and novel food ingredients, the SCF is asked to assess the safety, from the point of view of consumer health, of the genetically modified maize line GA21, with tolerance to the herbicide glyphosate.

6.5. Request in respect of Listeria monocytogenes in ready to eat foods

The Committee is requested to report on the extent to which it can support the conclusions and recommendations ¹ made by the Scientific Committee on Veterinary Measures related to Public Health to be extended to food of non-animal origin.

6.6. Request in relation to the evaluation of toxicological information related to the safety assessment of genetically modified tomatoes

In response to a parliamentary question to the Commission the Committee is requested to comment on the relevance of the findings provided by toxicological studies carried out in 1993 during the authorisation process for the Flavr Savr tomato in the US for the safety assessment of genetically modified tomatoes.

7. Draft report on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen

additional information on safety of creatine

The plenary had discussed a draft on this issue at the previous session. The Committee considered at that time that it was necessary to reconsider a number of issues in the appropriate Working Groups. The new version incorporated the changes addressing the issues raised at the previous session. After a discussion some further changes were agreed and the Committee considered the text as adopted.

The Committee also examined the safety of creatine on the basis of the work done by the Working Group on Additives. The Committee was of the view that the review on the safety of creatine supplementation should stand as separate opinion although it should be seen in connection to this opinion. A number of changes were examined. The Committee decided to send the draft back to the Working Group for preparation for the next plenary.

The full report on the composition and specification of food for sportsmen is attached to these minutes as <u>ANNEX I</u>.

8. Contaminants

8.1. Draft opinion on zearalenone

The Committee considered the draft prepared by the Working Group on Contaminants. After introduction of editorial changes the opinion was adopted. The differences between the TDI established by the SCF and the PMTDI for zearalenone derived by JECFA in 2000 were noted. This conclusion is based on additional information available to the SCF leading to the application of a higher safety factor and the establishment of a temporary TDI. In addition, the Committee recommends, among others, that additional studies should be performed to determine the no hormonal effect level in prepubertal pigs.

The text of the full opinion appears as **ANNEX II**.

9. Food Microbiology and Hygiene

Draft opinion on Listeria monocytogenes in ready to eat foods

The Committee discussed and adopted the draft prepared by the Working Group on Food Microbiology and Hygiene with editorial changes.

The text of the full opinion appears as **ANNEX III**.

10. Novel Foods

10.1 Exchange of views on the draft report by the Scientific Steering Committee on Emerging Health Issues - the case of genetically modified plants

The members of the Committee were asked to give their views on this draft report by the SSC. A summary of the views expressed will be brought to the SSC by the chairman of the Committee for its consideration.

10.2. Evaluation of toxicological information related to the safety assessment of genetically modified tomatoes

The Committee discussed a draft opinion produced *ad hoc* by one of its members. The revised text was referred to the Working Group on Novel Food for completion.

11. Additives

11.1. Draft opinion on sucralose

The Committee discussed new information (including two new studies) submitted by the petitioner in response to the issues that the Committee considered unresolved at the previous plenary session in March 2000.

The Committee expressed its strong regret that the two new study reports were not submitted upon their completion in mid 1999, when the Committee was known to be developing its opinion on sucralose, since they are very relevant for the overall safety evaluation.

The Committee considered that the additional information and the new studies submitted, although not the study suggested by the Committee, did address the remaining issues. The Committee decided to re-discuss a revised version of the draft opinion, incorporating the new studies submitted and the petitioner's recent response, at the next plenary. The revised draft will be prepared with the help of the Additives Working Group.

11.2. Requests in relation to purity criteria of food additives

11.2.1. Draft opinion on beta-cyclodextrin produced using CGTase from Paenibacillus macerans

The Committee examined the draft prepared within the Working Groups on Additives and on Food Microbiology. During the discussion a number of clarifications were introduced in the text and it was considered agreed.

The full opinion is attached to these minutes as **ANNEX IV**

11.2.2. Draft opinion on beta-cyclodextrin produced using CGTase from a recombinant Bacillus licheniformis

The Committee examined the draft prepared by the Working Groups on Additives, Food Microbiology and Hygiene, and Novel Foods. During the discussion a number of clarifications were introduced in the text and it was considered agreed.

The full opinion is attached to these minutes as ANNEX V

11.2.3. Draft opinion on crystalline beta carotene from Blakeslea trispora

The Committee examined the safety of this source of beta carotene by the Working Groups on Additives and Food Microbiology and Hygiene. The draft was discussed. A number of changes were introduced in the text. Subject to these changes the text was considered adopted.

The full opinion is attached to these minutes as **ANNEX VI**

12. Beta carotene

Discussion on beta carotene from all dietary sources

The Committee had evaluated beta carotene in 1975 as a food colourant and agreed with the JECFA ADI of 5 mg/kg bw day. The review of beta carotene had been prompted by the unexpected results in smokers in a number of recent intervention studies. The Committee was also looking at the establishment of an upper level for beta carotene.

The Committee examined a draft on the safety of beta carotene from all dietary sources which contained a comprehensive review of the studies available. After a discussion where a number of issues were raised that required some consideration, the plenary decided to modify the text to make it more focused and to clarify the reasoning behind the proposed recommendations. The revised draft would be reconsidered at the next plenary session.

13. Upper levels for vitamins and minerals. Progress report

- 13.1. Discussion of the guidelines for the evaluation of upper levels for vitamins and minerals
- 13.2. Discussion on an upper level for folate
- 13.3. Discussion on an upper level for manganese
- 13.4. Discussion on an upper level for molybdenum

The Committee considered the draft reports on the above mentioned subjects. Although there was broad consensus on the main evaluation for each of them, a number of details were identified requiring further consideration by the Task Force. The Plenary will consider the issues again probably at the next meeting.

14. Food Contact Materials

14.1. Draft opinion on the ninth additional list of monomers and additives for food contact materials

The Committee considered the draft submitted by the Working Group. The draft could not be discussed at the previous plenary because of lack of time to discuss it properly due to the heavy agenda.

After the discussion, the Committee agreed on some minor comments and adopted the draft opinion.

The full opinion is attached to these minutes as **ANNEX VII**

14.2. Draft opinion on the tenth additional list of monomers and additives for food contact materials

The Committee considered the draft opinion prepared by the Working Group. The Plenary agreed a number of changes and considered that subject to the incorporation of these changes the opinion could be adopted.

The full opinion is attached to these minutes as **ANNEX VIII**

15. Schedule of SCF meetings

Schedule for 2000

Dates for the following meetings of the plenary of the SCF were confirmed as recorded in the minutes of the previous meeting. The Committee will consider the schedule of meetings after the appointment of a new Committee in November 2000.

16. Comments on the European Food Authority

The comments prepared by the Committee by written procedure regarding the future European Food Authority proposed in the Commission's White Paper on Food Safety had been sent by the Chairman to the Commission.

The SCF's comments are included as APPENDIX to these minutes.

17. Work programme of the SCF

The extensive work programme for the present and future mandate of the Committee was noted.

18. General information from the Commission services

Information on the publication of the reports of the Committee

The secretariat reported on the publication of the 43 rd and 44 th reports of the SCF by the Office of Official Publications of the European Community (OPOCE). The 42 nd report was due to be published in the very near future. The secretariat also reported that the opinions adopted during the present mandate of the SCF since October 1997 will be published shortly in a comprehensive CD-ROM, together with the opinions of all the other sister scientific Committees.

19. Progress reports from Working Groups

The provisional dates for the meetings of the forthcoming working groups in 2000 are the following:

- Working Group on Additives: 5/6 July, 27/28 September.
- Working Group on Contaminants: 7 July, 29 September.
- Task Force on Dioxin: 10/11 July
- Working Group on Flavourings: 17/18 July, 23/24 October.
- Working Group on Food Contact Materials: 18/19/20 September, 27/28/29 November.
- Working Group on Food Microbiology and Hygiene: 3 July, 5 October.
- Working Group on Novel Foods and Processes: 3/4 July, 4 October.
- Working Group on Nutrition: 5 September, 13 December.
- Task Force on Upper Levels for Vitamins and Minerals: 12/13 July, 21 September

20. Any other business

The committee welcomed Miss Enza Agro as new collaborator in the SCF secretariat. It also expressed its recognition and appreciation for the invaluable work done for the Committee by Miss Jacqueline Thollebeke in the past two years.

21. Adoption of these minutes

These minutes were adopted at the 122 nd plenary session of the SCF on 7 September 2000

ANNEXES

- <u>ANNEX I</u>: Report on Food on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen (SCF/CS/NUT/SPORT/5 final)
- ANNEX II: Opinion on fusarium toxins part 2 ²: zearalenone (zea) (SCF/CS/CNTM/MYC/22 Rev.3 Final)
- ANNEX III: Opinion in respect of Lysteria monocytogenes
- <u>ANNEX IV</u>: Opinion on beta-cyclodextrin produced using cycloglycosyltransferase obtained from *Paenibacillus macerans* (SCF/CS/ADD/AMI 48 Final)

- <u>ANNEX V</u>: Opinion on beta-cyclodextrin produced using cycloglycosyltransferase from a recombinant *Bacillus licheniformis* (SCF/CS/ADD/AMI/52 Final)
- ANNEX VI: Opinion on crystalline beta carotene from *Blakeslea trispora* (SCF/CS/ADD/COL 158 Final)
- ANNEX VII: Opinion on the 9th additional list of monomers and additives for food contact materials (CS/PM/GEN/M81 Final)
- ANNEX VIII: Opinion on the 10th additional list of monomers and additives for food contact materials (CS/PM/GEN/M82 Final)

APPENDIX

Comments by the Scientific Committee on Food on the European Food Authority

SCF response to the Commission's paper on a future European Food Authority

(with a reference to the White Paper on Food Safety issued by the Commission of the European Communities 12 January 2000 and the report on a European Food and Public Health Authority, December 1999)

The Scientific Committee on Food is the oldest of the Scientific Committees in the European Communities, set up in 1974, and over the years experiences have accumulated although membership of the Committee has changed several times.

On the basis of these experiences, the present Committee would like to present its views on a future European Authority for scientific advice.

The White Paper on Food Safety proposes the establishment of an independent European Food Authority to improve and bring coherence to the corpus of legislation covering all aspects of food products from "farm to table".

The Commission also identifies a wide range of measures to improve food safety standards. The White Paper lists 59 actions to be implemented before the end of 2002. Legislation will be reviewed and amended as necessary to make it coherent, comprehensive and up-to-date.

The new Authority will, according to this vision, become the scientific point of reference for the whole Union, will contribute to a high level of consumer health protection, and consequently will help to restore and maintain consumer confidence.

The White Paper makes a strong argument for greater transparency at all levels of food safety policy to enhancing consumer confidence in EU Food Safety policy.

The above vision and proposals are strongly supported by the SCF.

1. However, the White Paper does not suggest a specific structure of the new institution to handle the food safety. Such a structure is suggested in the report of the *3 Wise Men* (A European Food and Public Health Authority, December 1999)

The report of the 3 Wise Men actually suggests a very precise structure for the Authority, which besides scientific advice on food, would also include scientific advice on public health and the environment. The background for the advisory function to include all scientific advice in one Authority is the urgent need to have a better, coherent and more stringent approach to public health in Europe, likewise for scientific advice regarding environment.

Whether this broader approach is justified is beyond the remit of discussion for the Scientific Committee on Food. The rest of the precise description of the structure of the Authority is still relevant for the consideration of SCF.

The arguments for the structure are very well focussed on the limitations of the present system and the needs for the future system based on the past experiences as well as the future needs due to increased focus of food safety in Europe.

The recommendations in the report are strongly supported by the present SCF.

- 2. Ensuring the safety and quality of food and the environment is a public health priority and the basis for optimization of nutritional status of the consumer. The adoption of appropriate food-based dietary guidelines, together with changing of life style as means of health promotion, will allow consumers to benefit. Issues of food safety and nutritional aspects should therefore, in the view of the SCF, be integrated tasks of a future food and public health authority.
- 3. There is a clear need to improve the efficiency of the scientific committees by using existing or to be formed networks in Member States to do the preparatory work. However in this case necessary provisions and precautions should be taken with respect to expertise as well as commitments. For instance, although the SCOOP projects have turned out to be positive in some areas, in other areas there appeared lack of expertise and/or lack of dedication in performing the work. Capacity building and mutual confidence in scientific assessments and data collection made within national institutions and national advisory structures are of primary importance here.

Moreover cooperation with other international bodies and committees should be encouraged since the scientific world does not stop at European borders.

Apart from this, the secretarial support of the Committee should be substantially enhanced, not only in number, but especially with respect to the scientific input and support in the preparation of draft opinions and scientific advice.

4. Regarding the structure of scientific advice the SCF recommends that the present size of the Committees of 18-20 members is kept since it allows a broad and at the same time significant detailed scientific expertise within each committee. For instance the SCF includes members covering toxicological, nutritional, microbiological, chemical expertise enabling in depth discussions both within the discipline and between disciplines.

The SCF supports the idea having one Steering Committee in the Authority composed of directly appointed members as well as the chairpersons from the Sectorial Committees for Food, Animal Health etc. since this will facilitate consideration of common issues, priority setting and co-ordination between Sectorial Committees.

Besides the Sectorial Committees the SCF suggests the formation of horizontal committees, which may not need to meet regularly, but may be called on for advice on an *ad hoc* basis. These committees could deal with particular issues such as general principles for risk assessment, allergy, immunotoxicology, molecular biology, carcinogenicity. They should deliver their reports to the Steering Committee for adoption. The final reports should be used as guidance documents by the different committees.

Each Sectorial Committee should be assisted in the preparation of working papers and draft opinions by working groups established in connection with the committee. The work of these working groups should be based on support from a network of national institutes in the field in question e.g. food toxicology, nutrition, food microbiology.

The number of Sectorial Committees should be kept as low as reasonably possible to avoid overlap.

- 5. The Communication of information to the public should include both the results of the scientific advice on risk and also the consequences of the risk management.
- 6. More emphasis should be given to the importance of how requests for scientific advice are formulated and their context. In some cases in the past they have been too fragmentary and formulated on legal reasoning which may not always be of real benefit for the consumer. Moreover committees after consultation should be in the position to reformulate the terms of reference of any request for advice, based on scientific expertise.
- 7. Given the importance of scientific advice as stated on several pages in the document, there should be a clear appreciation for those providing the advice.

This means on one hand the remuneration of the experts involved in providing the advice to and the time spend for the Commission, acknowledging that they can not work at the same time for the Commission and their own organization, and on the other hand an appreciation from the Commission in a non-material way which would ensure that the best

scientists in the Community are keen to participate in the work of the Scientific Committees.

¹ Opinion of the SCVPH on Listeria monocytogenes, expressed on 23 September 1999

² Opinion of the SCVPH on fusarium toxins part 2 zearalenone (zea) (SCF/CS/CNTM/MYC/22 Rev.3 Final)