

Minutes of the 111th Meeting of the Scientific Committee on Food held on 18 -19th March 1998 in Brussels

ATTENDANCE LIST - LISTE DES PARTICIPANTS - TEILNEHMERLISTE

Members/Membres/Mitglieder

- Mme. S. BARLOW
- MM. D. BOSKOU,
- A. CARERE,
- I. ELMADFA (2nd.Vice-Chairman, Vice-President, Stellv. Vorsitzender)
- Mme. A. FERRO-LUZZI
- MM. A. FLYNN,
- R. FRIES,
- W. GRUNOW
- Mme. A. KNAAP (1st. Vice-Chairman, Vice-President, Stellv. Vorsitzender)
- MM. KNUDSEN (Chairman, President, Vorsitzender),
- S. LINDGREN,
- B. MOSELEY,
- A. PALOU,
- W. SARIS,
- P. TOBBACK,
- P. VERGER,
- J.-M. WAL

Apologies/Excusés/Entschuldigt

- none

Commission/Kommission

- Mr. P. J. WAGSTAFFE (DG XXIV/B/3)
- Mr. C. DECKART (DG XXIV/B/1)
- Mr. B. SAMANIEGO (DG XXIV/B/3)
- MM. B. MATHIOUDAKIS (DG III/E/1),
- L. ROSSI (DG III/E/1)
- Mme. S. HEINIMAA (DG III/E/1),
- Mme C. MAJEWSKI (DG III/E/1)

Secretariat/Serétariat/Sekretariat

- Mr. M. A. GRANERO ROSELL (DG XXIV/B/3)
- Mr. P. DASKALEROS(DG XXIV/B/2)
- Mme. J. THOLLEBEKE (DG XXIV/B/3)

Adoption of the agenda

The draft agenda was adopted

Apologies for absence

None

Declarations of interest

None

Matters arising from the minutes of the 110th meeting

The Chairman reported that following his report about the SCF plans on activities regarding risk assessment/risk management interface and on intake & exposure to the Scientific Steering Committee, the SSC had decided to take up those initiatives as interdisciplinary activities.

Actions following from opinions and recommendations; General information from the Secretariat

Mme Heinimaa from DG III, the Commission service responsible for the legislation on food additives, reported that the opinion of the SCF on cross linked carboxymethyl cellulose had been very useful for the Commission to take position in relation to the Council's Common Position on the modification of Directive 95/2.

SCF Organisational matters

6.1. Changes in the Secretariat

Mr. Wagstaffe reported to the Committee the changes in the secretariat. Mr. Wagstaffe had been appointed Head of Unit B3 within DG XXIV/B from the beginning of March. The Committee has since then been managed by Unit B3 and not by Unit B2. The Secretary of the Committee is now Mr. Granero, who reinforced the Secretariat in November. Mr. Wagstaffe's new responsibilities involved four Scientific Committees including the SCF. Mr. Wagstaffe thanked the members of the Committee for the enriching close cooperation having been carried out during the last 5 years. The Committee also expressed to Mr. Wagstaffe its strong appreciation for his work as Secretary of the Committee.

The changes in the Secretariat involve also changes at the clerical level. The Committee welcomed Mme Jacqueline Thollebeke as new member of the Secretariat team.

The SCF expressed the wish that the Secretariat should have its entire staff in office as soon as possible.

6.2. Rules of procedure for the SCF

The Secretariat introduced a new version of the draft rules of procedure. Due to a lack of time it was not possible to finalise the discussion. The item was therefore deferred for next plenary. Comments from the members will be collected by the Secretariat and put together by the Chairmanship before the next Plenary.

6.3. Information on reimbursement of expenses and indemnities

The Committee expressed deep concern about the long delays in the reimbursement of expenses and indemnities. After a round table it was apparent that many of the members had not been reimbursed yet their expenses even from the

meeting of November. The Secretariat indicated that DG XXIV had transmitted to the relevant Commission services all the necessary information concerning the reimbursement of expenses of all the meetings of the SCF up to the end of February. The Commission services will pursue this question in order to solve this problem. It was agreed that the members would send to the secretariat a list of the meetings for which they have not been reimbursed.

6.4. Plenary and WG Meeting dates for 1998

The revised schedule of meetings, now including the meetings of the Nutrition WG, was adopted.

6.5. SCF Information pack (updated)

The Secretariat introduced a revised information package on the scope, responsibilities and organisation of the SCF and a complete list of previous opinions. The changes in the secretariat were also included there. An earlier version had been distributed at the previous Plenary session.

6.6. Follow-up on the use of e-mail by the SCF

The secretariat reported that due to the changes in the secretariat team the first tests to put the system in operation could not be carried out for this plenary session as scheduled. The secretariat will report on developments in this area at the next meeting.

New requests for opinions since the last meeting

The Secretariat circulated the terms of reference for the dossiers "Microbiological standards for soups and broths (notification of new Spanish legislation within the Hygiene Directive)", "Cholera in vegetables and fruit", and irradiation. The first two were referred to the WG on Food Microbiology and Hygiene and the third to the WG Novel Foods and Processes (see item 11.3). As regards copper in calf liver, already discussed extensively at the last Plenary session, the discussions will follow in the WG contaminants.

The question on 4 hexyl resorcinol could not be discussed due to lack of terms of reference.

Opinion on the applicability of the ADI to infants

Discussion was deferred to the next meeting due to lack of time.

Food Additives

9.1. Progress report from the Working Group

The Chair of the Group reported about the on-going activities in the Group. The Group is carrying out evaluations of a number of food additives and other substances. The Group was also making progress in the revision of the SCF guidelines for the evaluation of food additives. Although some parts of the guidelines had been already revised there was still substantial work to be carried out.

9.2. Opinion on zinc acetate as a flavour enhancer in chewing gum

The Commission had requested the SCF to advice about the safety in use of zinc acetate as a food additive (flavour enhancer) in chewing gum. The rapporteur introduced the draft report.

After some discussions mostly on the relationship between nutritional and toxicological aspects of the dossier some changes were introduced in the draft opinion that was finally adopted.

The Committee considers "that the use of zinc acetate as a flavour enhancer in chewing gum products in concentrations up to 1 mg zinc acetate-dihydrate (corresponding to 0.30 mg zinc) per 1000 mg chewing gum centres is acceptable because of the non toxicity of zinc at the expected exposure level and the fact that the resulting intake is well below the nutritional requirement."

[The full opinion is included as Annex I.](#)

9.3. Mineral hydrocarbons

The Committee had adopted an opinion on mineral and synthetic hydrocarbons on 22 September 1995. The Committee used the 90-day studies available to set one full and one temporary Tolerable Daily Intake (TDI) to cover residues in food arising from the use of certain mineral hydrocarbons. The SCF stated that continued use of the ~~se~~ materials covered by the t-TDI was conditional on submission of a long term study completed within 5 years of the date of the SCF review. Since then a long-term carcinogenicity study from Japan has been published but it did not address all of the Committee's questions. The petitioner has informed the SCF of the schedule of new long term studies, which commenced in 1997, and has requested an extension of the time limit stated in the opinion to the year 2001. The Committee considers that is reasonable to extend this time limit and notes that the extra safety factor used in the evaluation due to the temporary nature of the TDI will be maintained in the meantime.

Materials and Articles in Contact with Food

10.1. Progress report from the Working Group

The Chairperson of the Working Group informed the Committee about the work being undertaken by the Group. She outlined the efficient way this Working Group has been in operation for many years. In this area of food contact materials, a very systematic approach has to be adopted in order that the SCF is capable of evaluating the thousands of substances used.

On request by the Chair of the WG, Mr. Rossi, the official responsible for legislation of food contact materials in DG III, explained the basic options chosen in the preparation of a draft Commission proposal for the fifth amendment of Directive 90/128. The Committee did notice the draft amendment and the reasons for its current approach and recommended to the Commission services to introduce as soon as possible all the substances evaluated by the SCF in EC legislation.

10.2 Evaluation of an additional list of substances for food contact materials

The Chairperson of the WG introduced the report and explained the way the Group had prepared the evaluation of this additional list of substances for Food Contact Materials. The report was adopted, with some editorial changes.

The Committee expressed its appreciation for the work performed by the WG members.

[The full opinion is given in Annex II.](#)

Novel Foods and Processes (including irradiated food)

11.1. Progress report from the Working Group

The Chairman of the WG reported on the first meeting of the group since the new mandate of the SCF. The Group is at present working in two different areas: Novel Foods and Irradiation.

11.2 Novel foods

No dossiers on novel foods have been submitted to the SCF since the new mandate. The desirability for updating the recent SCF guidelines for the evaluation of novel foods was discussed. Two approaches were suggested; one is to use the guidelines to assess the first dossiers submitted to the Committee and to identify areas where they might need revision, the second, to update them before dossiers are submitted. Areas where such revision might be necessary include the application of the concept of substantial equivalence and the precise meaning of postmarket surveillance. This discussion will continue in detail in the Working Group and the Commission will provide guidance.

11.2.1 Evaluation of three genetically modified maize plants and one genetically modified rape by the Scientific Committee on Plants.

The Committee was informed of the evaluation carried out by the Scientific Committee on Plants (SCP) on four genetically modified plants (Maize Monsanto, Maize Novartis, Maize AgrEvo, and Rape AgrEvo) within the framework of Directive 90/220 on the deliberate release into the environment of genetically modified organisms.

It was the understanding of the SCF that applications on the novel food use regarding these four plants might be presented to the Committee at a later point in time in accordance with the Regulation (EC) 258/97 on novel foods and novel food ingredients, in which case the Committee will be consulted if there is disagreement between Member States undertaking the initial evaluation.

The conclusions of the evaluations made by the SCP and the Commission's Press Release on this matter (BIO/98/62, 12/2/98) might thus be misinterpreted by the general public to include food safety matters although the safety of the use of the plants as foodstuffs has not been specifically assessed in accordance with the Regulation (EC) 258/97 on novel foods and novel food ingredients so far.

11.3. Evaluation of safety of irradiated foods

The Chairman of the Working Group reported on the 8 dossiers that had been provided to the Working Group. First impressions were that the dossiers were somewhat dated and incomplete and this might make the safety assessment more protracted.

The Secretariat circulated the terms of reference. The opinion of the SCF should be ready for the end of June taking into account the likely final adoption of the Directive on food irradiation. The urgency of the opinion and the characteristics of the dossiers represented significant difficulties in the work of the Committee in this case. A special *ad hoc* meeting to examine the dossiers in detail was confirmed for 27 April, as previously discussed in the Working Groups Novel Foods and Hygiene and Microbiology.

Food Microbiology and Hygiene

12.1. Progress report from the Working Group

The Chairman of the WG reported on the on-going work of the Working Group. The risk assessment for microbiological hazards is an emerging area for work in the Group.

The members received a copy of the booklet recently published by the Commission compiling, on the one hand, the SCF "Recommendation on the principles for the development of risk assessment of microbiological hazards under Directive 93/43/EEC concerning the hygiene of foodstuffs", and, on the other, the SCF and Scientific Veterinary Committee (Public Health Section) "Recommendation on principles for the development of microbiological criteria for animal products and products of animal origin intended for human consumption". This was a request by the WG as this is a very useful reference material now available in a handy format.

12.2. Opinion on *Aeromonas hydrophila* and *A. caviae* in natural mineral water.

The Commission had asked the SCF for advice on the potential microbiological risk associated with the presence of *A. hydrophila* and *A. caviae* in natural mineral waters (as defined in Council Directive 80/777/EEC).

Within the framework of the Directive 93/43 on Hygiene, Italy had informed the Commission and the other Member States of new Italian legislation introducing provisionally temporary levels for *Aeromonas* in natural mineral waters.

The Committee discussed the draft opinion prepared by the WG. The Committee concluded that " *A. hydrophila* and *A. caviae* in natural mineral water do not present a potential risk to human health. It therefore does not believe that limits for *Aeromonas* (*Aeromonas hydrophila* and *A. caviae*) in natural mineral waters can be justified even as a precautionary measure. The microbiological safety of natural mineral waters depends on the measures prescribed in Council Directive 80/777 and principally on protection of the source water and the processing plant from contamination. However, it seems likely that *Aeromonas* are a natural contaminant of such waters and thus will occur from time-to-time and be capable of growing in such waters when extracted and bottled. The potential of growth of contamination flora in bottled water is a separate question, which could lead to the use of other management options, such as consumer information."

[The full opinion is given in Annex III.](#)

Contaminants

13.1 Progress report from the Working Group

The Chairman of the Working Group reported on the main dossiers currently being considered by the Group. Besides the current dossiers, as an urgent matter the SCF had been asked to provide an updated evaluation of Ochratoxin A. He reported about a special *ad hoc* meeting with external widely known experts on this mycotoxin, scheduled for the week after this plenary session. This meeting would help substantially in the preparation of the updated opinion that should be ready for consideration at the next Plenary in June.

Nutrition and Dietetic Foods

14.1. Progress report from the Working Group

The chairman of the Working Group reported on the activity of the Group. The main objective of the first initial meeting had been the identification of tasks within the SCF Working Programme for 1998. The Commission services are going to issue requests for opinions in the area of foods for athletes and diabetic food. It is expected that the SCF will also receive later in the year a request to examine the setting of safety based upper levels for nutrients. Another area might be foods for very low calorie diets (300-400 Kcal.).

The revision of the 1992 guidelines on the Recommended Dietary Intakes might be considered also although the magnitude of the workload involved in the revision has to be examined. An involvement of the Member States, possibly through the Scientific Cooperation, and of other international organizations or fora was desirable taking into account the size of the task. This task would be undertaken if requested by the Commission.

Another potential area is the development of food based dietary guidelines. The WG also indicated that there is an ambitious DG V project in this area. Some of the members of the SCF participate in this activity but the SCF is not involved at present.

The WG will prepare a document defining clearly the different areas in which the Working Group will start working, for consideration at the next Plenary session.

14.2. Report on Beta-carotene - High dose studies

This report had been already discussed in the previous plenary (see minutes of the 110th Plenary). The Rapporteur presented, as agreed, a revised text incorporating the items requested at the previous Plenary. Some additional changes to the document were suggested and with this modifications the report was adopted. The summary and conclusions of

the report are as follows:

"The Committee has reviewed in detail the published studies on the use of β -carotene supplementation in combination with tocopherol, retinol and ascorbate in clinical and chemopreventive trials. In clinical trials doses up to 180 mg/day and in chemopreventive trials up to 50 mg/day were given.

Most of the chemopreventive trials with β -carotene alone and in combination with tocopherol, retinol or ascorbate in well-nourished population groups showed no protective effects against malignant neoplasms, cardiovascular disease or death from all causes. On the contrary, an increase of lung cancer incidence (18-28 %) and more overall death (8-17 %) were seen in smokers ingesting over long periods of time (4-8 years) supplements of 20 mg β -carotene per day.

The Committee cannot identify any specific explanation for these unexpected findings and therefore reconfirms its earlier concern expressed at the 107th meeting regarding the use of β -carotene supplements.

The Committee recommends that research is initiated to resolve the issue as a matter of urgency and thereby allowing the establishment of an upper safe limit for β -carotene intake both alone and in combination with other antioxidants to be used for the general public and for special population groups at risk."

[The text of the full report is included as Annex IV.](#)

The Committee will formulate its opinion on β -carotene at a later point in time.

Flavours

Due to lack of time, only a brief discussion on this item took place. The Commission's official responsible for the legislation on flavours informed the Committee that some Member States had submitted their national lists to the Commission. The question of updating the SCF guidelines before starting to evaluate substances or whether to use another approach was posed. It was concluded that the Commission services will present terms of reference for this area at the next plenary meeting.

Intake and Exposure

After a short discussion on the need for a model for exposure to chemicals that could be used for many different areas of activity of the SCF and may be by other Scientific Committees, Prof. Verger accepted to prepare a paper for next Plenary including a catalogue or list of tasks ranging from general to precise areas that could serve as a basis for orientating future work of the Committee in this area.

Scientific Co-operation

No matters were raised.

Information on the Fifth RTD Framework Programme and issues relevant for the SCF. COM(97) 553 final

The representative of DG XII, X. Goenaga, introduced the Commission proposal for the Fifth RTD Framework Programme and the Commission working paper on the specific programmes COM(97) 553 final, in particular, the research areas most relevant to the activities of the SCF. He reported about the changes introduced during the on-going institutional negotiations.

Within the specific programme "The living world and the ecosystem" most of the key actions have links with Food Safety, such as the key actions "Health, Food and Environmental factors", "The Cell Factory" and "Sustainable Agriculture Fisheries and Forestry", as well as some of the RTD activities of generic nature. In addition, Mr Goenaga

gave some examples of running projects funded by the FAIR programme that are relevant to issues currently being dealt with by the SCF.

The possibility of the SCF to contribute to the preparation of the specific programmes and workprogrammes was examined. This may be particularly relevant if the SCF identifies areas where lack of knowledge or of data makes it difficult to carry out proper risk assessments.

Ways by which closer collaboration between the RTD programmes and the activities of the SCF could take place in the most appropriate practical terms will be explored.

The Working Groups should consider this item in their agendas of forthcoming meetings to draw up a list of possible areas where research under the 5th R&D Framework in their specific fields could be considered for next plenary.

Any other business

Phthalate migration from soft PVC toys and child-care articles

The Committee took note that one member of the SCF had been asked to contribute to the Working Group of the Scientific Committee on Toxicity, Ecotoxicity and the Environment scheduled for 20/3/98 to discuss the above mentioned subject. This followed the request by the Scientific Steering Committee. The SCF has evaluated phthalates at different occasions.

These minutes were adopted by written procedure.

ANNEXES

- **ANNEX I:** [Opinion on zinc acetate as a flavour enhancer in chewing gum.](#)
- **ANNEX II:** [Evaluation of an additional list of substances for food contact materials.](#)
- **ANNEX III:** [Opinion on *Aeromonas hydrophila* and *A. caviae* in natural mineral water.](#)
- **ANNEX IV:** [Report on Effects of \$\beta\$ -Carotene Supplementation in Combination with Tocopherol and Ascorbate in Clinical and Chemopreventive Trials.](#)