Minutes of the 123 rd Plenary Meeting of the Scientific Committee on Food held on 16 - 19 October 2000 in Brussels

ATTENDANCE LIST / LISTE DES PARTICIPANTS / TEILNEHMERLISTE

Members/Membres/Mitglieder

Mrs. S. BARLOW, Mr. A. CARERE, I. ELMADFA (2 nd Vice-chairman, Vice President, Stellv. Vorsitzender), Mrs. A. FERRO-LUZZI, Mr. A. FLYNN (17/10 and thereafter), R. FRIES (18/10), W. GRUNOW, Mrs. A. KNAAP (1 st Vice-chairman, Vice President, Stellv. Vorsitzender), Mr. I. KNUDSEN (Chairman, President, Vorsitzender), S. LINDGREN (present on 17/10 and 18/10), B. MOSELEY (present on 17/10 pm and thereafter), K.-H. NAU (present on 16/10 and 17/10), A. PALOU (present on 18/10 pm and thereafter), W. SARIS (present on 17/10 and 18/10), P. TOBBACK (present on 17/10 pm and thereafter), P. VERGER (present on 17/10 pm and thereafter), J.-M. WAL (present on 18/10 pm and thereafter), R. WALKER (present on 17/10 pm and thereafter)

Experts:

J. ALEXANDER (present on 17/10 and thereafter, items 7 & 8), A. DI DOMENICO (present on 17-18/10, item 7), J.C. LARSEN (present on 17-18/10, item 7), A. RENWICK (present on 18 and 19/10, item 8), G. SPEIJERS (present on 17/10, item 7), H. VAN DEN BERG (present on 19/10, item 8)

Apologies for absence:

D. BOSKOU

Commission/Kommission

Mr. R. BATES (DG Fishery), Mr. L. ROSSI (DG Health and Consumer Protection), Mrs. C. SANDVIK (DG Health and Consumer Protection), Mr. F. VERSTRAETE (DG Health and Consumer Protection)

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

Mr. M.A. GRANERO ROSELL, D. PETTAUER, D. LIEM, M. ROMARÍS, Mrs. H. PEDERSEN

1. Apologies for absence

Apologies were received from D. Boskou.

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 122 nd meeting

The draft minutes of the 122 nd plenary meeting held on 6 and 7 September 2000 were discussed and accepted after the introduction of a few corrections.

5. Matters arising since last Plenary

Mr. Granero introduced the new members of the Secretariat. Dr. D. Liem joined the team recently. He is a seconded national expert from the Netherlands. He has collaborated with the Committee in the past. Dr. Romarís, a biologist, also joined recently the team on a temporary basis. They both are already helping supporting several working groups of the Committee. Lastly, Mme Hanne Pedersen replaced Mme Enza Agro.

6. General information from the Commission services

The Commission services, at the occasion of the possibly last meeting of the present mandate wished to thank the members of the Committee for their hard work during the last three years of mandate. On behalf of the Commission services, Mr. Peter Wagstaffe, Head of the Unit C/3 "Management of Scientific Committees II; scientific co-operation and networks", responsible for the management of several Scientific Committees including the SCF addressed the Committee highlighting some facts regarding its the activity during the present term.

The SCF has held during these three years 15 plenary sessions and nearly 100 meetings of Working Groups of the SCF. This represents about 360 meeting days. More than 70 additional experts have contributed with their expertise to supplement that of the members of the Committee. Besides the already very important amount of time spent discussing in meetings, there is also a very substantial amount of time devoted to the preparation and study of dossiers that are then reported and discussed in the meetings themselves. During this period the Committee has celebrated its 25 years anniversary of existence since the Scientific Committee for Food was created in 1974.

Mr. Wagstaffe made a balance of the Committee's output in the last three years. The Committee has issued more than 70 opinions relating to more than 200 substances or compounds in food during this last three years. These opinions cover many different areas where the Commission has sought the advice of the Committee mainly with the purpose of creating or adapting legislative measures. In many of these cases, the measures are included in the programme of the White Paper on Food Safety. In a number of cases, the request for advice by the Commission has come with urgency and the Committee has in all cases responded in an efficient and timely manner. To name a few of these *urgent requests*, he mentioned the question of the levels of acceptable pesticide residues in baby food, the so called "negative list" for GM products, and the question of the dioxin contamination incident in Belgium, and the recent request about the invocation of the safeguard clause under the Novel Food Regulation by the Italian government.

The opinions adopted by the Committee in this period comprise full evaluations of a number of important *contaminants* such as dioxins (being discussed at this meeting) and a number of mycotoxins: ochratoxin A, zerealenone, deoxynivalenol, fumonisin and nivalenol. The Commission has used or is using this advice to incorporate it in the appropriate legislation.

The Committee has also examined some aspects of the *microbiological risks* in the food supply, in particular the case of *Listeria monocytogenes, Vibrio cholera* in certain foodstuffs, *Aeromonas* in natural mineral waters or potential microbiological contamination of soups and consommés.

In the new area of *novel foods*, the Committee has evaluated a genetically modified tomato, has issued advice on the

products derived from genetically modified organisms but where no presence of DNA or protein can be detected, and has examined the scientific arguments by the Italian authorities regarding the suspension of the marketing of a number of products. The Committee has also evaluated a number of novel foods not related to genetic manipulation: phytosterol esters in fat spreads, a new egg yolk, nangai nuts, *Stevia rebaudiana* leaves.

In the field of *dietetic foods and nutrition*, the Committee has provided the scientific basis for the directives on pesticide residues in baby foods, the directive for specific foods for sportspeople and the directive on nutrient sources that may be used in the different dietetic foods. The Committee has been working very thoroughly during this period in the area of establishing upper levels for vitamins and minerals. This area is becoming very important in view of the ongoing debate about food supplements and food fortification. As in many other areas these are also measures foreseen in the White Paper. The Committee also addressed the question of the unexpected results of the chemopreventive studies with beta carotene and has carried out a detailed review of the safety of beta carotene. The Committee also looked into the safety aspects of the addition of high amounts of caffeine, taurine, and glucuronolactone to certain socalled energy drinks.

The Committee has evaluated or re-evaluated the safety of a number of *food additives* in this period. Among them, there are five sweeteners and also other additives. The Committee has also examined a substantial number of dossiers relating to new or alternative manufacturing processes of existing authorised additives, for which companies have asked the Commission to modify the existing specifications. Again the Commission has used the advice when preparing updates or modifications of the relevant legislation.

The Committee has also provided advice to the Commission on the area of *flavourings*. It has advised the Commission on setting up the programme for evaluation of chemically identified flavouring substances registered in the Community. It has also re-evaluated the safety of coumarin.

The Committee has continued with its evaluation of the *food contact materials*, the majority of which are plastic materials. More than 150 substances have been evaluated or re-evaluated during this period by the Committee.

The applicability of the ADI approach when evaluating chemicals such as food additives that could be consumed by babies and infants had also been discussed by the SCF.

Besides working in the SCF, members of the Committee have also actively contributed to the other sister Scientific Committees where this has been necessary. This has happened at the level of plenary meetings and working groups of the Scientific Steering Committee, the Scientific Committee on Plants, the Scientific Committee on Veterinary measures relating to Public Health, the Scientific Committee on Animal Nutrition and the Scientific Committee on Toxicity and Ecotoxicity and the Environment.

The SCF has also contributed to the debate about the future Food Authority issuing some comments.

Far from having finished its tasks, the Committee has still a heavy workload in front. The future looks promising and it is clear that the expertise of the Committee and its members will continue to serve the public interest in the area of food safety, likely in better and more efficient manners.

Mr. Wagstaffe ended by thanking the members of the SCF not only for the mass of work accomplished as mentioned before but also for the permanent spirit of constructive collaboration with the Commission services.

Both the Commission services and the Committee wished to thank the experts who have supplemented the expertise of the Committee in this period for specific issues for their kind and precious collaboration. The list of additional experts appears as appendix I to these minutes.

7. Contaminants

7.1. Risk assessment of dioxins and dioxin-like PCBs in food. Draft opinion

The comprehensive draft report was introduced by the chair of the Task Force on Dioxins. During the thorough discussions the Committee identified a number of issues that required detailed further consideration. The Committee could therefore not agree on a final text and decided that the remaining issues should be addressed by a smaller group consisting of SCF members and experts. The revised report would then be considered at the next plenary meeting. According to the provisional schedule this meeting would be held under the new mandate of the SCF.

The Committee noted that the Commission will propose measures on dioxins and PCBs in food on the basis of the scientific opinion of the SCF.

7.2. Fusarium toxins - fumonisin B1. Draft opinion

The rapporteur introduced the draft opinion prepared by the Working Group on Contaminants. There was general satisfaction among the members about the contents of the opinion. During the discussion a few editorial remarks were made and it was agreed to include more information with respect to the dietary exposure of the general population. The Committee recalled that a SCOOP exercise has recently been started to collate and compile data on the occurrence of fumonisin B1 in foodstuffs.

The draft opinion on fumonisin B1 was adopted after the introduction of amendments proposed during the discussion. The full text of this opinion appears as Annex I to these minutes.

7.3. Fusarium toxins - nivalenol. Draft opinion

The rapporteur introduced the draft opinion prepared by the Working Group on Contaminants. The report was adopted after introduction of minor editorial changes.

The Committee noted that a group assessment of fusarium toxins will be carried out after completion of the evaluation of the individual toxins. The full text of this opinion appears as Annex II to these minutes.

8. Upper levels for vitamins and minerals

8.1. - Draft guidelines for the development of upper levels of intake for vitamins and minerals

The rapporteur introduced the draft guidelines as prepared by the Task Force already discussed at an earlier plenary session.. During the discussion a number of clarifications were introduced in the text. Once the issues were resolved and subject to the incorporation of them in the text, the guidelines were adopted. They appear as Annex III.1 to these minutes.

The Committee also discussed how to express clearly the ongoing work for the remaining of the 29 vitamins and minerals not yet evaluated this time and how this task will be completed in the future.

8.2. - Draft opinion on the upper level for beta carotene

An earlier draft had already been discussed at the previous plenary. After discussion the draft was adopted with some further minor changes. The full opinion appears as Annex III.2 to these minutes

8.3. - Draft opinion on the upper level for vitamin B_2

The draft was presented and discussed. During the discussion, a number of studies that might have an impact on the derivation on an upper level were identified that needed detailed consideration. The Committee decided to send the draft back for further consideration of these elements.

8.4. - Draft opinion on the upper level for folate

The consideration of the upper level for folate had been already discussed at an earlier plenary meeting. During the discussion some mostly editorial changes were identified. The text was considered agreed. The full opinion appears as Annex III.3 to these minutes.

8.5. - Draft opinion on the upper level for vitamin B_6

The draft was introduced by the rapporteur and discussed. The final text was adopted after the inclusion of a few modifications. The full text appears as Annex III.4 to these minutes.

8.6. - Draft opinion on the upper level for vitamin B_{12}

The draft presented by the rapporteur was introduced. It was discussed and a certain number of changes were agreed to make clear the opinion of the Committee on the upper level for this vitamin. The full text appears as Annex III.5 to these minutes.

8.7. - Draft opinion on the upper level for selenium

The rapporteur presented the changes in the draft opinion introduced after the discussion in the last plenary. A few amendments were proposed in the sections on critical effects derivation of the upper level, and the risk characterisation. The opinion was adopted after the introduction of the changes proposed. It appears as Annex III.6 to these minutes.

8.8. - Draft opinion on the upper level for manganese

The rapporteur presented the changes in the draft opinion introduced after the discussions at the last plenary. A number of further amendments were considered. The final text was agreed. It appears as Annex III.7.

8.9. - Draft opinion on the upper level for molybdenum

The Committee had held a discussion on the upper level for molybdenum at an earlier meeting and decided to come back to it when a number of other micronutrients were also discussed. A number of changes to the draft were discussed to make it more clear.

The final opinion appears as Annex III.8 to these minutes.

9. Novel Foods

9.1. - Draft opinion on bacterial dextrans

A previous draft had been presented at the last SCF plenary meeting and had been referred back for further consideration of some details. The new draft was presented by the rapporteur and was adopted, pending inclusion of minor mostly editorial remarks that were discussed and agreed. The full text of this opinion appears as Annex IV to these minutes.

10. Food contact materials

10.1. - Update of the SCF guidelines for the evaluation of food contact materials of 1990: Draft "Presentation of an application for assessment of a substance to be used in food contact materials prior to its authorisation"

Due to lack of sufficient time, this item could not be discussed and therefore was postponed.

10.2. - Draft opinion on the 11 th list of monomers and additives for food contact materials

The Chairman of the Working Group introduced the draft opinion prepared by the Group. subject to a number of editorial changes the text was adopted. The full text appears as Annex V to these minutes.

10.3. - Opinion on a survey on intakes of di-2-(ethylhexyl) adipate (DEHA)

The draft prepared by the Working Group was introduced and discussed. Subject to a number of presentational changes to clarify the issue the final text was adopted. The full text appears as Annex VI to these minutes.

11. Additives

11.1. - Updating of the existing guidelines (1992): Draft guidance on submissions for food additive evaluations by the SCF

Due to lack of time, this item had to be postponed.

11.2 - Statement on benzoates and parabens

The Committee evaluated benzoic acid and benzoates (E210-213) (Opinion on benzoic acid and its salts) in its opinion of 25 February 1994 (35 th series of reports of the SCF, 1996). The Committee established at the time a temporary ADI of 0-5 mg/kg bw, as the sum of benzoic acid and its salts, expressed as benzoic acid. The Committee commented that a study to investigate clastogenic activity *in vivo* was needed and a study to investigate teratogenicity was desirable. Information on consumer intakes of benzoic acid and its salts was also needed.

The Committee evaluated also at the same time the parabens, (E214-220), (Opinion on *p*-hydroxybenzoic acid alkyl esters and their sodium salts, 25 February 1994, 35 th series of reports of the SCF, 1996). It established a temporary ADI of 0-10 mg/kg bw, as the sum of methyl, ethyl and propyl *p*-hydroxybenzoic acid and their sodium salts. The Committee commented that a cell proliferation study in the rat forestomach and a rat teratology study were needed. Information on consumer intakes of parabens was also needed.

The Committee expressed in both opinions the wish to review the situation within 3 years. The Committee wishes to indicate that it has not yet received any submission regarding these two groups of additives but still wishes to review their safety, taking account of any new toxicological data including the studies requested in the 1994 opinions. In view of the time that has now elapsed, the Committee will consider withdrawing the temporary ADIs for these substances if the requested information is not provided within the next 12 months.

In the meantime, the Committee wishes to emphasise that the existing safety information on these substances gives sufficient reassurance that current uses are temporarily acceptable and that these additives perform an important preservative function in foods. Furthermore the Committee notes that benzoic acid is found naturally, albeit at relatively low levels, in foods such as fruits, and that benzoate is a normal product of intermediary metabolism.

12. Statement on coumarin

Further to its opinion of 1999 on coumarin (expressed on 22 /9/99), the Committee has received information about recently completed toxicity, metabolic and mechanistic studies and has been informed about progress in relevant ongoing research. These studies are regarded as particularly pertinent to the issues raised by the Committee in its 1999 opinion with respect to the mode of action of coumarin and interspecies differences in toxicity. The Committee was informed that the ongoing studies should be completed within 12 months and would wish to review the study reports

when available. In the meantime, the Committee reiterates the request in its 1999 opinion for a study of in vivo DNA-binding and DNA-adduct formation in rats in the relevant target organs, in order to help to clarify the mode of action. The Committee also reiterates its recommendation that current extent and levels of use should not increase.

13. Any other business

No other business was discussed.

14. Adoption of these minutes

These minutes were adopted at the 124 th plenary meeting of the SCF on 21 November 2000.

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, not in the section outcome/minutes).

ANNEX I: Opinion of the SCF on fumonisin B1 (SCF/CS/CNTM/MYC/24Final)
ANNEX II: Opinion of the SCF on nivalenol (SCF/CS/CNTM/MYC/26 Final)
ANNEX III:
Annex III.1: SCF Guidelines for the development of Tolerable Upper Intake Level for vitamins and minerals (SCF/CS/NUT/UPPLEV/11 Final)
Annex III.2: Opinion of the SCF on the Tolerable Upper Intake Level of beta carotene SCF/CS/NUT/UPPLEV/37 Final
Annex III.3: Opinion of the SCF on the Tolerable Upper Intake Level of folate SCF/CS/NUT/UPPLEV/18 Final
Annex III.4: Opinion of the SCF on the Tolerable Upper Intake Level of vitamin B_6 SCF/CS/NUT/UPPLEV/16 Final
Annex III.5: Opinion of the SCF on the Tolerable Upper Intake Level of vitamin B_{12} SCF/CS/NUT/UPPLEV/42 Final
Annex III.6: Opinion of the SCF on the Tolerable Upper Intake Level of selenium SCF/CS/NUT/UPPLEV/25 Final
Annex III.7: Opinion of the SCF on the Tolerable Upper Intake Level of manganese SCF/CS/NUT/UPPLEV/21 Final
Annex III.8: Opinion of the SCF on the Tolerable Upper Intake Level of molybdenum SCF/CS/NUT/UPPLEV/22 Final
ANNEX IV: Opinion of the SCF on bacterial dextrans (SCF/CS/NF/DOS/7 Final)
ANNEX V: Opinion of the SCF on the 11 th list of monomers and additives for food contact materials (SCF/CS/PM/GEN/M83 Final)
ANNEX VI: Opinion of the SCF on a survey on dietary intake of the food contact material di-2-(ethylhexyl) adipate (DEHA) (SCF/CS/PM/3276 Final /31920)

APPENDIX

List of additional experts who have supplemented the expertise of the Committee for specific issues in the period November 1997- November 2000.

Prof. Dr. J. ALEXANDER	National Institute of Public Health, Oslo, Norway
Dr. V. AZAIS-BRAESCO	Institut National de la Recherche Agricole (INRA) CRNH UMMM, Centre de Clermont-Ferrand/Theix, France
Dr. A. BERG	Med. Universitätklinik, Universität Freiburg, Freiburg, Germany
Dr. C. BÖHME	Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (BgVV), Berlin, Germany
Dr. J. CARSTENSEN	Copenhagen, Denmark

Dr. J-J. CASTEGNARO	International Agency for Research on Cancer (IARC), Lyon, France
Dr. L. CASTLE	Ministry of Agriculture Fisheries & Food, Central Science Laboratory, York, United Kingdom
Dr. P. COOK	Department of Health, London, United Kingdom
Dr. R. CREBELLI	Istituto Superiore di Sanitá, ISS, Roma, Italy
Prof. D. DAVIES	Imperial College of Science, Technology and Medicine, The Hammersmith Hospital, London, United Kingdom
Dr. A. DI DOMENICO	Istituto Superiore di Sanitá, Roma, Italy
Dr. G. DIRHEIMER	Institut de Biologie Moléculaire et Cellulaire du CNRS, Strasbourg, France
Dr. B. DUSEMUND	BgVV, Berlin, Germany
Prof. Dr. P. ELIAS	Karlsruhe, Germany
Dr. A. FEIGENBAUM	DS NHSA-INRA, Paris, France
Dr. P. FÜRST	Chemisches Landes und Staatliches Veterinäruntersuchungsamt, Münster, Germany
Prof. Dr. R. GILBERT	London, United Kingdom
Dr. J. GREIG	Department of Health, London, United Kingdom
Dr. K. GROB	Kantonales Labor, Zürich, Switzerland
Dr. J. GRY	Veterinær- og Fødevaredirektoratet (VFD), Søborg, Denmark
Dr. D. GÜRTLER	BgVV, Berlin, Germany
Dr. T. HALLAS-MØLLER	VFD, Søborg, Denmark
Prof. Dr. W. HAMMES	Institut für Lebensmitteltechnologie, Stuttgart, Germany
Dr. J. HERITAGE	University of Leeds, Leeds, United Kingdom
Dr. N-G. ILBÄCK	Levsmedelsverket (NFA), Uppsala, Sweden
Dr. JACQUIN NAVARRO	Laboratorio de Coexphal, Almería, Spain
Prof. S. KARENLAMPI	University of Kuopio, Kuopio, Finland
Dr. O. LADEFOGED	VFD, Søborg, Denmark
Dr. C. LAGRUE	Centre STIFL de St-Rémy, St.-Rémy, France
Dr. J.C. LARSEN	VFD, Søborg, Denmark
Prof. J.-C. LHUGUENOT	ENSBANA, Dijon, France
Dr. A.K.D. LIEM	Rijksinstituut voor Volksgezondheid en Milieu (RIVM), Bilthoven, The Netherlands
Prof. R. MAUGHAN	University Medical School, Aberdeen, United Kingdom
Dr. A. MANTOVANI	ISS, Roma, Italy
Dr. M. MEIJERINK	RIVM, Bilthoven, The Netherlands
Dr. W. MENNES	RIVM, Bilthoven, The Netherlands
Dr. O. MEYER	VFD, Søborg, Denmark
Dr. R. MITCHELL	PHLS Environmental Communicable Disease Surveillance Centre, London, United Kingdom
Dr. A. MORTENSEN	VFD, Søborg, Denmark
Dr. C. MULHOLLAND	Department of Health, London, United Kingdom
Dr. J.-F. NARBONNE	Laboratoire de Physico-Toxicochimie des Systèmes Naturels, Université de Bordeaux, Bordeaux, France
Dr. C. NGUYEN-THE	INRA-Station de technologie des produits végétaux, Avignon, France
Dr. S. NOTERMANS	TNO Nutrition and Food Research, Zeist, The Netherlands
Prof. D. PARENT-MASSIN	ESMISAB, Plouzane, France
Dr. P.-L. PENTTILA	National Food Administration of Finland, Helsinki, Finland
Dr. E. RASMUSSEN	VFD, Søborg , Denmark

Prof. A. RENWICK	University of Southampton, Southampton, United Kingdom
Dr. R. RIJK	TNO Nutrition and Food Research, Zeist, The Netherlands
Prof. E. RODRIGUEZ-CEREZO	Centro Nacional de Biotecnología, Madrid, Spain
Dr. D. SCANDELLA	CTIFL, Runigs, France
Prof. C. SCHLATTER	Zürich, Switzerland
Prof. J. SCHLATTER	Bundesamt für Gesundheitswesen, Switzerland
Dr. E. SCHMIDT	BgVV, Berlin, Germany
Dr. K. SCHUMANN	Walther Strauss Institut, Institut für Pharmakologie und Toxikologie, Munich, Germany
Dr. J. SHAVILA	Department of Health, London, United Kingdom
Prof. N. SKOVGAARD	Birkerod, Denmark
Dr. G. SPEIJERS	RIVM, Bilthoven, The Netherlands
Dr. A STAMMATI	ISS, Roma, Italy
Dr. J. STEADMAN	London, United Kingdom
Dr. I. THORUP	VFD, Søborg, Denmark
Dr. J.G.M. VAN ENGELEN	RIVM, Bilthoven, The Netherlands
Dr. H. VAN DEN BERG	TNO Nutrition and Food Research, Zeist, The Netherlands
Dr. F. VAN LEUSDEN	RIVM, Bilthoven, The Netherlands
Dr. F.X.R. VAN LEEUWEN	WHO European Centre for Environment and Health (ECEH), Bilthoven, The Netherlands
Dr H. VAN LOVEREN	RIVM, Bilthoven, The Netherlands
Dr. P. VOYSEY	Chipping Campden Food Research Association, Chipping Campden, United Kingdom
Prof. Dr J. G. VOS	RIVM, Bilthoven, The Netherlands
Dr. A. WAGENMAKERS	Universiteit van Maastricht, Maastricht, The Netherlands
Prof. C. WILLIAMS	Loughborough University, Loughborough, United Kingdom
Prof. R. ZITO	Istituto Regina Elena, Rome
Dr. F. ZUCCO	Istituto di Tecnologie Biomediche, CNR, Roma, Italy