Scientific Committee on Food

SCF/CS/PLEN/MINS/137
14 May 2003

Minutes of the 137th Plenary Meeting
of the
Scientific Committee on Food

held on 2/3/4 April 2003 in Brussels

http://europa.eu.int/comm/food/fs/sc/scf/index_en.html
Members/Membres/Mitglieder
Mr. J. ALEXANDER (present on 2-3 April)
Mrs. S. BARLOW Vice Chair
Mr. A. CARERE
K-H. ENGEL
A. FLYNN
W. GRUNOW
T. HIRVI
Mrs. A. KNAAP Chair
Mr. B. KOLETZKO
J.C. LARSEN
S. LINDGREN
B. MOSELEY
A. PALOU Vice Chair
W. SARIS (present on 3-4 April)
J. SCHLATTER (present on 3-4 April)
P. TOBBACK
P. VERGER
J.-M. WAL
R. WALKER

Experts
Mr. P. ELIAS (present on 3-4 April)
J. GRY (present on 3 April)
W. MENNES (present on 3 April)
Mrs. A. POETING (present on 3 April)
H. PRZYREMBEL (present on 4 April)

Commission/Kommission (DG Health and Consumer Protection)
Mr. A. KLEPSCH
Mrs. H. LEE
Mr. S. MAGAZZU
B. MATHIOUDAKIS
G. SCHREIBER
D. VAN BREMPT
Mrs. R. VEALE

Secretariat/Secrétariat/Sekretariat (DG Health and Consumer Protection)
Mrs. T. SATSERI
Mr. D. LIEM
Mrs. P. RODRIGUEZ IGLESIAS
Mrs. C. HEPPNER
Mr. T. HALLAS-MØLLER
Mrs. H. PEDERSEN
1. **WELCOME, APOLOGIES FOR ABSENCE**

   The Chair welcomed the participants. There were no apologies for absence.

2. **ADOPTION OF THE AGENDA**

   It was agreed to insert an agenda item 14 to discuss the transfer of all remaining requests from the SCF to the EFSA rather than to have a separate discussion of "progress reports" for each of the different working groups. The agenda was adopted with this modification.

3. **DECLARATIONS OF INTEREST**

   Professor Berthold Koletzko declared an interest on agenda item "revision of essential requirements of infant formulae and follow-on formulae". He had been a consultant for a producer of infant formulae. The Committee considered that Professor Koletzko could attend during the discussion of the opinion.

   Professor Sven Lindgren declared an interest in probiotics (agenda item "revision of essential requirements of infant formulae and follow-on formulae"). The Committee considered that Professor Lindgren could attend during the discussion of the opinion.

   Professor Ron Walker declared an interest in agenda items "rosemary extract as antioxidant" and 'isopropyl alcohol". He had been a consultant for a manufacturer of the proposed additives. Professor Walker's attendance during the concerning agenda items was not further discussed because for this last meeting these items were on the agenda for information of the Committee members only (cf. agenda item 5).

4. **CO-ORDINATION WITH THE SCIENTIFIC STEERING COMMITTEE AND OTHER SCIENTIFIC COMMITTEES**

   The chair informed the Committee about the outcomes of the most recent plenary meeting of the Scientific Steering Committee (SSC). A document on harmonisation of risk assessment procedures is almost finalised and will be submitted for adoption at the next meeting of the SSC.

   At its previous meeting the SSC also discussed the continuation of the activities of the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers, the Scientific Committee on Toxicity, Ecotoxicity and the Environment,
The Committee was also informed about the outcomes of a meeting organised by the Scientific Committee on Animal Nutrition, in which some SCF members participated, to develop a decision tree to evaluate whether or not certain feed additives of microbiological origin could be given a GRAS (‘generally recognised as safe’) status. A draft procedure was established which will be placed on the homepage of the SCAN with a request for comments.

The Committee was also informed that the Scientific Committee on Veterinary Measures relating to Public Health (SCVMPH) discussed a draft opinion on Salmonellae at its plenary meeting of 26-27 March. The draft opinion on Salmonellae in the food chain had been prepared by a joint working group of the SCVMPH and the SCF and the SCVMPH will continue its discussions at its last plenary meeting in April.

5. NEW DOSSIERS

_The Committee agreed to include the following four dossiers in the working programme of the Committee. However, considering the imminence of the transfer of responsibilities regarding scientific advice from the Commission to the European Food Safety Authority, these dossiers would thus be transmitted to the EFSA._

5.1. Rosemary extract as antioxidant

The Health and Consumer Protection Directorate-General has received a request from the European Rosemary Extract Manufacturers Group to use rosemary extracts as an anti-oxidant in foodstuffs. Extracts of the plant rosemary can have both flavouring and anti-oxidative properties. In cases where the processing of the rosemary extract can be optimised to enhance the anti-oxidative function and to reduce that of flavouring these products are considered as food additives and therefore require authorisation under Directive 95/2/EC. The Committee is asked to evaluate the safety of rosemary extracts as an anti-oxidant in foodstuffs.
5.2. **Pullulan**

The Health and Consumer Protection Directorate-General has received a request to use pullulan as a new food additive and to include it in the Annex IV of Directive 95/2/EC. The Committee is asked to evaluate the safety in use of pullulan as food supplements (foodstuffs in capsule and coated tablet form) or as flavoured edible films (breath-freshening edible films).

5.3. **Isopropyl alcohol**

The Health and Consumer Protection Directorate-General has now received a request from the European Flavour & Fragrance Association to use isopropyl alcohol (propan-2-ol) as a solvent for flavourings. The Scientific Committee on Food has adopted an opinion on some extraction solvents on 21 June 1991. The Committee considered then propan-2-ol (isopropyl alcohol) acceptable as a food extraction solvent but in the absence of any supporting data could not establish a full acceptable daily intake at that time. The Committee is asked now to evaluate the safety in use of isopropyl alcohol as a solvent for flavourings.

5.4. **Goat’s milk for infant formulae**

The Health and Consumer Protection Directorate-General has received a request concerning the use of goat’s milk protein as a protein source in infant formulae and in follow-on formulae. The current legislation on infant formulae and follow-on formulae (Directive 91/321 as amended by Directive 96/5/EC) only permits the use of cows’ milk, soya protein isolates and partially hydrolysed protein as the protein sources in infant formulae and follow-on formulae. The Committee is asked to evaluate the safety in use of goat’s milk protein as a source of protein in infant formulae and in follow-on formulae.

6. **FOOD ADDITIVES**

6.1. **Soybean hemicellulose**

The draft opinion prepared was presented and discussed. The document was adopted subject to incorporation of a few modifications proposed by the Committee.

The text of the full opinion appears as **Annex I** of these minutes.
6.2. Glycyrrhizinic acid

The draft opinion was presented by the rapporteur and discussed. The document was adopted subject to incorporation of a few modifications proposed by the Committee. The Chair expressed the Committee's appreciation for the extensive work done by the rapporteur.

The text of the full opinion appears as Annex II of these minutes.

6.3. L-serine and some amino acid-amino acid salts for use in foods for particular nutritional purposes

On 19 May 1999 the SCF adopted an opinion on substances for nutritional purposes which have been proposed for use in the manufacture of foods for particular nutritional uses (‘PARNUTS’). Since then, the Commission received a request to add a number of nutritional substances in view of an amendment of Commission Directive 2000/15/EEC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses. Of these the Committee now evaluated L-serine and salts of individual amino acids.

A draft statement was presented by the chair of the Additives Working Group and discussed. The Committee agreed with the proposed statement. The text of the full statement appears as Annex III of these minutes.

6.4. D-alpha-Tocopheryl acid succinate

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

Further information was submitted by the petitioner but it was not sufficient to clarify the extent of hydrolysis of TAS. At its 122nd Plenary meeting on 6-7 September 2000 the Committee agreed to extend its acceptance for a further two years, 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. A further submission was received in 2001 informing the Committee that an \textit{in vitro} hydrolysis study on TAS had been conducted but had not demonstrated complete hydrolysis. The petitioner had therefore offered to conduct an \textit{in vivo} study to address both the bioavailability issue and the possible effects of TAS, should any be absorbed intact.

In view of this, the Committee decided to recommend extension of the temporary acceptance of TAS for a further 2 years, with the provision that the results of the proposed study are submitted within one year to the European Commission/EFSA for evaluation.

The full statement appears as \textbf{Annex IV} of these minutes

\section*{6.5. Statement on p-hydroxybenzoic acid alkyl esters and their sodium salts (Parabens)}

A draft statement was presented by the chair of the Additives Working Group and discussed. The Committee proposed a few changes and agreed on the following final statement:

Parabens have been used as preservatives in food for over 50 years. Under EU Directive 95/2/EC, Annex III, the parabens (E214-219) are conditionally permitted for use in a limited number of foods in combination with either sorbates or sorbates and benzoates, i.e. in jelly coatings of meat products, surface treatment of dried meat products, cereal- or potato-based snacks and coated nuts, confectionery (excluding chocolate), and liquid dietary food supplements. They are not permitted for use as the sole preservative in any foods.

Following a review of the published literature, the SCF expressed an opinion on the parabens in 1994 in which it concluded that the available data showed some inadequacies and uncertainties (Reports of the Scientific Committee for Food, Thirty-fifth series). A temporary ADI of 0-10 mg/kg bw was allocated for the sum of methyl, ethyl and propyl p-hydroxybenzoic acid and their sodium salts. Further studies in the rat to investigate cell proliferation in the forestomach and developmental toxicity were requested.

The situation was reviewed again in 2000 when the Committee reiterated its wish to review the safety of both benzoates and the parabens (Minutes of the 123\textsuperscript{rd} Plenary Meeting of the SCF, October 2000). Subsequently, data were submitted by industry in support of the benzoates and a favourable opinion
allocating a group ADI for the benzoates was adopted (Minutes of the 134th Plenary Meeting of the Scientific Committee on Food, September 2002). No data have been submitted in support of the parabens.

It is unclear whether the lack of support for the parabens indicates that they are no longer used in food sold in the EU. The Committee recommends that the Commission take steps to ascertain whether or not the parabens are still used in food before any further scientific advice is sought. In the event that the parabens are still used in food, the Committee draws attention to its statement of October 2000, that the temporary ADI should be withdrawn if no further data are submitted.

This statement also appears as Annex V of these minutes.

7. **FOOD CONTACT MATERIALS**

7.1. **Opinion on the 22\textsuperscript{nd} list of monomers and additives for food contact materials**

The draft opinion prepared was presented by the chairman of the Food Contact Materials Working Group and discussed. The document was adopted subject to incorporation of the changes suggested by the Committee.

The text of the full opinion appears as Annex VI of these minutes.

7.2. **Opinion on the 23\textsuperscript{rd} list of monomers and additives for food contact materials**

The draft opinion prepared was presented by the chairman of the Food Contact Materials WG and discussed. The document was adopted subject to incorporation of the changes suggested by the Committee.

The text of the full opinion appears as Annex VII of these minutes.

8. **FLAVOURINGS**

8.1. **Isosafrole**
The draft opinion was presented by the rapporteur and discussed. The document was adopted subject to incorporation of the changes suggested by the Committee.

The text of the full opinion appears as Annex VIII of these minutes.

### 8.2. Precursors of hydrocyanic acid

A draft minutes' statement on precursors of hydrocyanic acid in flavourings and other food ingredients with flavouring properties was prepared by the Flavourings Working Group. It was presented by the rapporteur and discussed. The Committee proposed a few changes and agreed on the following final statement:

The Committee is asked to advise the Commission on substances used as flavourings or present in flavourings or present in other food ingredients with flavouring properties for which existing toxicological data indicate that restrictions of use or presence might be necessary to ensure safety for human health. In particular, the Committee is asked to advise the Commission on the implications for human health of hydrocyanic acid (HCN) in the diet.

Hydrolytic enzymes (ß-glycosidases) are capable of liberating HCN from cyanogenic glycosides. Enzymic hydrolysis can occur as a result of the release of ß-glycosidases following maceration of plant tissues, or by the gut microflora after ingestion. Hydrolysis liberates the corresponding aglycone, which further breaks down non-enzymically to HCN and the respective carbonyls.

On the basis of a draft working document the Committee considered both experimental animal data and several epidemiological studies in cassava-eating populations exposed to high levels of the cyanogenic glycoside linamarin. However, overall the data were not considered adequate to establish a numerical NOEL or TDI in humans for chronic exposure to HCN.

The Committee concluded that the current exposure to cyanide from flavouring ingredients would not give rise to acute toxicity. However, in view of the lack of adequate data on chronic toxicity, the Committee supports the continued application of limits to the levels of total HCN in foods.

This statement also appears as Annex IX of these minutes.

### 9. Tolerable Upper Intake Levels for Vitamins and Minerals

#### 9.1. Tolerable upper intake level of Calcium
The draft opinion prepared was presented and discussed. The document was adopted subject to incorporation of changes as suggested during the discussion by the Committee.

The text of the full opinion appears as **Annex X** of these minutes.

### 9.2. Tolerable upper intake level of Chromium

The draft opinion prepared was presented and discussed. The document was adopted subject to incorporation of changes as suggested during the discussion by the Committee.

The text of the full opinion appears as **Annex XI** of these minutes.

### 9.3. Tolerable upper intake level of Vitamin E

The draft opinion prepared was presented and discussed. The document was adopted subject to incorporation of changes as suggested during the discussion by the Committee.

The text of the full opinion appears as **Annex XII** of these minutes.

### 9.4. Tolerable upper intake level of Vitamin K

The draft opinion prepared was presented and discussed. The document was adopted subject to incorporation of changes as suggested during the discussion by the Committee.

The text of the full opinion appears as **Annex XIII** of these minutes.

### 9.5. The limitations of extrapolating tolerable upper intake levels of nutrients for children

A draft minutes’ statement addressing the limitations of extrapolating tolerable upper intake levels of nutrients for children was presented and discussed. The Committee proposed a few changes and agreed on the following statement:
“The Committee recognises limitations in the extrapolation of tolerable upper intake levels (UL) of nutrients from those established for adult populations to children, based solely either on body weight or on body surface area. For some nutrients, the Committee concluded that an extrapolation on the basis of body weight or body surface area would yield UL for children that were incompatible with known nutrient requirements and refrained from recommending an UL for children. Physiological differences between adults and young children, especially at a young age, are both quantitative and qualitative in nature. Existing differences in substrate absorption, metabolism, deposition in tissues during growth, and renal or other excretion that may affect UL of nutrient intakes are not always closely related to body size. The Committee recommends this issue be reviewed in order to establish whether further refinements in the approach or further research are needed.”

This statement also appears as Annex XIV of these minutes.

10. NUTRITION

10.1. Revision of essential requirements of infant formulae and follow-on formulae

The rapporteur presented the new parts of the draft opinion which were introduced since the Committee’s 136th plenary meeting. During the discussions, the Committee proposed a few modifications. The Committee adopted the opinion pending incorporation of the changes suggested during the discussions.

The text of the full opinion appears as Annex XV of these minutes.

11. NOVEL FOODS AND NOVEL PROCESSES

11.1. Food irradiation

The rapporteur presented the changes in the draft opinion since the discussions of a previous draft at the Committee’s 136th Plenary Meeting. The document was adopted subject to incorporation of changes as suggested during the discussion by the Committee.

The text of the full opinion appears as Annex XVI of these minutes.
11.2. Applications for approval of plant sterol-enriched foods

The draft opinions were presented and discussed. The documents were adopted subject to incorporation of changes as suggested during the discussion by the Committee.

The text of the full opinions appears as Annex XVII and Annex XVIII of these minutes.

12. CONTAMINANTS

12.1. Potential risk to human health arising from substances proposed as acceptable previous cargoes

The draft opinion prepared was presented and discussed. The document was adopted subject to incorporation of changes as suggested during the discussion.

The text of the full opinion appears as Annex XIX of these minutes.

12.2. Fumonisin B1, B2 and B3

A draft minutes' statement on Fumonisin B1, B2 and B3 was presented and discussed. The text was adopted subject to incorporation of a few changes as suggested during the discussions. The Committee agreed to consider the document as an updated opinion on Fumonisins.

The text of the full opinion appears as Annex XX of these minutes.

13. GENERAL INFORMATION FROM THE COMMISSION SERVICES

The Commission services, at the occasion of the last meeting of the SCF wished to thank the members of the Committee for all the hard work they have carried out in the last 2.5 years. On behalf of the Commission services, Mr. Robert Coleman, Director-General of the Health and Consumer Protection Directorate-General, highlighted certain facts regarding the activities of the SCF since its existence from 1974.

The SCF was the first of the scientific committees formally established by the Commission in 1974. Its task was to provide the Commission with independent and
irreproachable scientific advice on matters of consumer safety, essentially to facilitate
the free movement of foodstuffs within the “Common market”.

The earliest work concerned food additives. The work rapidly grew in parallel with
the growth of community legislation. The food sector was the first to systematically
require mandatory consultation of a scientific committee before the Commission
could make proposals on consumer health issues. This approach ensured that the SCF
was kept fully occupied with problems as diverse as food packaging, contaminants,
solvents, irradiation, food hygiene, baby food, novel food, GM maize and even BSE in
baby food in 1996.

For almost thirty years the SCF has enjoyed a well-earned reputation as the primary
scientific authority on matters in its field and for the highest level of independence.
During its 137 plenary meetings, the SCF has adopted more than 340 reports and
opinions.

Mr. Coleman explained that this illustrious period was drawing to a close and the
work of the SCF would shortly be taken over by the EFSA. Even in its final days, the
Committee continued to work at an extraordinary rate. Since 2000, when the
Committee started its mandate, it had adopted more than 80 opinions and statements
and even at the final session the Committee was still adopting a further 20. This in
itself is ample evidence of the high level of professionalism and responsibility that
characterises the work of the Committee. The SCF has also demonstrated its capacity
to respond urgently to matters of high consumer and political concern, for example on
dioxins in 2000 and again on acrylamide in 2002.

Mr. Coleman was very pleased to have the opportunity to thank all the Committee
Members on behalf of the Commission for the tremendous contribution that the
Committee and their predecessors have made to the cause of consumer safety.

He especially mentioned Peter Elias for outstanding dedication to the scientific
committees. Dr. Elias, was present as a Member at the very first SCF meeting in 1974
and has been active ever since as a Member of the SCF, SCAN or as an expert in a
working group.

Mr. Coleman expressed also the appreciation of the great efforts that have been made
to ensure the smooth transfer of responsibilities to the EFSA and especially to
complete so many outstanding questions.

On behalf of the Committee the Chair thanked Mr. Coleman for his speech. The Chair
also wished to thank the present and the former Scientific Secretaries and the
colleagues from the legislative services of the Commission for the co-operation over
the years.

Furthermore the Chair emphasised that the Committee was only able to deliver the
huge amount of opinions and statements through the continuous willingness and
ability of the members and the experts in the working groups and task forces of the
Committee to deliver their inputs. The sometimes heavy scientific debates, both in and
outside the meetings, did however not interfere members being colleagues and friends,
for which she was grateful.

14. TRANSFER REPORT

The Secretariat prepared a document containing an overview of requests for scientific
advice of the Commission which have not yet been considered or finalised by the
Committee and will therefore be transferred to the appropriate Panels of the European
Food Safety Authority (EFSA).

The Committee noted the progress made so far in the Task Forces on Food Allergy
and on Organotin Compounds. Despite all efforts and the progress made it was
unfortunately not possible to finalise the work before the end of the term of the
Committee. The Committee expressed its gratitude for the extensive work that has
been done and encourages the EFSA to continue and finalise the work as soon as the
new Scientific Panels start their activities.

In addition to these specific dossiers the Committee wished to draw the attention of
EFSA also to pending general questions, especially with respect to further
improvements in the risk assessment procedures. In particular, the Committee wished
to reiterate the statement made in the minutes of its 132nd Plenary Meeting of 15-17
April 2002 concerning current approaches for assessment of the health risks of
substances considered to be genotoxic and carcinogenic.

15. ADMINISTRATIVE INFORMATION

The Committee discussed the draft minutes of its 136th Plenary Meeting, which was
held on 3-5 March in Brussels. The minutes were adopted subject to incorporation of
a few changes suggested by the Committee.

16. ANY OTHER BUSINESS
There was no other business discussed.

17. ADOPTION OF THESE MINUTES

These minutes were adopted by written procedure on 14.5.2003.
ANNEXES

(The text of the opinions and statements adopted in these annexes appear on the web page of the SCF on the Internet; the opinions appear in the section outcome/opinions of the web page and the statements appear in the section outcome/minutes of the web page of the SCF)

ANNEX I
Opinion of the Scientific Committee on Food on Soybean Hemicellulose (expressed on 4 April 2003). SCF/CS/ADD/EMU/185 Final

ANNEX II
Opinion of the Scientific Committee on Food on Glycyrrhizinic acid and its ammonium salt (expressed on 4 April 2003). SCF/CS/ADD/EDUL/225 Final

ANNEX III
Statement of the Scientific Committee on Food on L-serine and some amino acid-amino acid salts for use in food for particular nutritional purposes (expressed on 4 April 2003). SCF/CS/ADD/NUT/55 Final

ANNEX IV

ANNEX V
Statement of the Scientific Committee on Food on the Parabens (expressed on 4 April 2003). SCF/CS/ADD/CONS/53 Final

ANNEX VI
Opinion of the Scientific Committee on Food on the 22nd additional list of monomers and additives for food contact materials (expressed on 4 April 2003). SCF/CS/PM/GEN/M94 Final

ANNEX VII
Opinion of the Scientific Committee on Food on the 23rd additional list of monomers and additives for food contact materials (expressed on 4 April 2003). SCF/CS/PM/GEN/M95 Final

ANNEX VIII
Opinion of the Scientific Committee on Food on Isosafrole (expressed on 4 April 2003). SCF/CS/FLAV/FLAVOUR/30 Final
ANNEX IX
Minutes’ statement of the Scientific Committee on Food on precursors of hydrocyanic acid in flavourings and other food ingredients with flavourings properties (expressed 4 April 2003). SCF/CS/FLAV/FLAVOUR/48 Final

ANNEX X
Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Calcium (expressed on 4 April 2003). SCF/CS/NUT/UPPLEV/64 Final

ANNEX XI
Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Trivalen Chromium (expressed on 4 April 2003). SCF/CS/NUT/UPPLEV/67 Final

ANNEX XII
Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin E (expressed on 4 April 2003). SCF/CS/NUT/UPPLEV/31 Final

ANNEX XIII
Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin K (expressed on 4 April 2003). SCF/CS/NUT/UPPLEV/32 Final

ANNEX XIV
Minutes’ statement of the Scientific Committee on Food addressing the limitations of extrapolating tolerable upper intake levels of nutrients for children (expressed on 4 April 2003). SCF/CS/NUT/UPPL/68 Final

ANNEX XV
Opinion of the Scientific Committee on Food on the revision of essential requirements of infant formulae and follow-on formulae (expressed on 4 April 2003). SCF/CS/NUT/IF/65 Final

ANNEX XVI
Revision of the opinion of the Scientific Committee on Food on the irradiation of food (expressed on 4 April 2003). SCF/CS/NF/IRR/24 Final

ANNEX XVII
Opinion of the Scientific Committee on Food on an application for approval of plant sterol-containing foods (expressed on 4 April 2003). SCF/CS/NF/DOS/23 Final

ANNEX XVIII
Opinion of the Scientific Committee on Food on an application for approval of plant sterol-containing foods (expressed on 4 April 2003). SCF/CS/NF/DOS/24 Final
ANNEX XIX
Updated opinion of the Scientific Committee on Food on the potential risk to human health arising from the transport in ships’ tanks of oils and fats from substances proposed as acceptable previous cargoes (expressed on 4 April 2003). SCF/CS/CNTM/CARGO/16 Final

ANNEX XX
Updated opinion of the Scientific Committee on Food on Fumonisin B1, B2 and B3 (expressed on 4 April 2003). SCF/CS/CNTM/MYC/28 Final