



EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions

C2 - Management of scientific committees; scientific co-operation and networks

Scientific Committee on Food

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SCF/CS/PLEN/MINS/127

4 July 2001

**Minutes of the 127th Plenary Meeting
of the
Scientific Committee on Food**

Held on 29/30 May 2001, Brussels

These minutes were adopted at the 128th meeting of the SCF on 10/11 July 2001.

ATTENDANCE LIST LISTE DES PARTICIPANTS TEILNEHMERLISTE

Members/Membres/Mitglieder

Mr. J. ALEXANDER
Mrs. S. BARLOW First Vice chair
Mr. A. CARERE
 K-H. ENGEL
 A. FLYNN (present on 30th May)
 W. GRUNOW
 T. HIRVI
Mrs. A. KNAAP Chair
Mr. B. KOLETZKO
 J.C. LARSEN
 S. LINDGREN (present on 29th May)
 B. MOSELEY
 A. PALOU Second Vice chair
 J. SCHLATTER
 P. TOBBACK
 P. VERGER
 J.-M. WAL
 R. WALKER

Apologies for absence:

Mr. W. SARIS

Commission/Kommission

Mr. L. ROSSI (DG Health and Consumer Protection)
Mrs. K. NEUBAUER “ “
Mr. F. VERSTRAETE
 M. SLAYNE
 G. SCHREIBER

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

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

1. Apologies for absence

The apologies were noted.

2. Adoption of the agenda

The scheduled item on salatrim was postponed as the Working Group, meeting the day before the Plenary, wished to include some additional clarifications in the draft submitted to the Plenary previously. With this change the agenda was adopted.

3. Declarations of interest

There were none.

Matters arising from previous plenary meeting

There were none.

4. New dossiers

- organotins (contaminant)
- polycyclic aromatic hydrocarbons (contaminant)
- soybean hemicelullose (food additive)
- beta cyclodextrin obtained using CGTase from a genetically modified strain of E. coli K12 (food additive)
- DMDC in alcoholic beverages
- safety considerations of specifications containing limits of ethylene oxide of certain food additives
- re-evaluation of glycyrrhizic acid on the basis of new information (food ingredient and chemically defined flavouring)
- evaluation of additional information on creatine
- evaluation of additional studies in relation to the SCF's opinion on caffeine, taurine and gamma glucuronolactone in so called energy drinks

The following new dossiers have been added to the working programme of the Committee:

The Commission Services are considering to propose the establishment of maximum levels for *organotin* compounds and *polycyclic aromatic hydrocarbons* in food at Community level, based on the legal framework of Council Regulation EEC 315/93. The Commission therefore seeks the advice of the SCF on the risks to human health from exposure to these compounds in the diet. The Committee considered establishing ad-hoc working groups given the size of these tasks.

The Commission Services have received a request to include *soybean hemicellulose* in the Community legislation under the framework Directive 89/107/EEC on food additives. The SCF is asked to evaluate the safety of soybean hemicellulose as a food additive, as emulsifier, thickener, stabiliser and anti-caking agent.

The Commission services have received a request to modify the existing specifications of *beta cyclodextrin* to include a new production method *using CGTase from a genetically modified strain of E. coli K12*. The Committee is asked to examine the safety in use of this new source of beta cyclodextrin.

The Committee evaluated *dimethyl dicarbonate* (DMDC) for use in non-alcoholic beverages in 1989 and 1996. DMDC is permitted in the EU in non-alcoholic beverages, non alcoholic wine and liquid tea concentrate up to 250 mg/l added amount, no residues detectable, according to Directive 95/2. This legislation is based on the evaluation by the SCF carried out. These two opinions only address the safety in use of DMDC in non-alcoholic beverages (fruit juices). The Commission services have received information on wine sterilisation using DMDC. The Committee is asked to indicate if its conclusions on the safety of DMDC used in non-alcoholic beverages is also applicable to its use in wine.

The SCF is currently reconsidering the safety in use of ethylhydroxyethyl cellulose (EHEC) as a food additive in the light of the potential presence of *ethylene oxide*, *1,4-dioxane*, *ethylene chlorohydrine*, and *mono- and diethylene glycol as impurities*. The presence of these impurities in EHEC resulted in an increased concern of the Commission about the possibility that other authorised food additives such as the polyoxyethylene sorbitan esters (polysorbates) may also contain these substances as impurity. A screening of the chemical specification of food additives currently included in the Community legislation resulted in a selection of polyoxyethylene sorbitan esters (polysorbates) and polyethylene glycol which may contain some of the earlier specified impurities at levels of possible concern. The SCF is asked to give advice on the safety of this issue.

The Commission Services have been made aware of recent results of a human study on *glycyrrhizic acid*, which might provide the information as requested by the SCF in its opinion on this compound expressed in 1991. Ammonium glycyrrhizate is included in the Register of Chemically Defined Flavouring substances. A dossier has been submitted to the Commission Services. The Committee is asked to review this additional information and to update its opinion of 1991 on the safety of this substance as an ingredient in foodstuffs. The Committee is also asked to evaluate the safety of ammonium glycyrrhizate as a chemically defined flavouring substance as included in the Register.

Since the Committee adopted its opinion on safety aspects of *creatine* supplementation on September 2000, new information and evaluations have appeared. The Committee is requested to assess this information to establish if there is a need to modify its opinion expressed in September 2000.

The Commission services have received two animal studies on a so called energy drink. The Committee is asked to review these studies and to verify it is needs to modify its opinion of 1999 on *caffeine, taurine and gamma glucuronolactone in energy drinks*.

The Committee had also received the formal terms of reference for the updating of its existing report on *irradiation* of 1986, as there are a number of significant scientific and technical developments since that date. The mandate required some clarification and the Commission services agreed to revise it accordingly.

5. General information from the Commission services on matters relevant to the SCF

The Secretariat explained that representatives of the Commission Services would be available during the discussion of specific agenda items to update the Committee on legislative developments affecting the work of the SCF.

6. Co-ordination with the SSC and other Scientific Committees

6.1. Feed-back by the Chair on subjects discussed in the SSC which are of interest to the Committee

The Chair updated the Committee on relevant issues under discussion by the SSC.

6.2. Feedback by members of the Committee having attended working group meetings of other Scientific Committees.

No meetings of the SSC with attendance of SCF members took place since the last plenary.

6.3. Contribution by the SCF to harmonisation of risk assessment procedures

The Committee considered the papers prepared by the task force of the SSC on harmonisation of risk assessment procedures on the structure of opinions and the glossary of key terms. A number of comments and suggestions on both items were collected for consideration by the SSC.

6.4. Feed-back on the work of the Joint Working Group on GMOs/Novel Food/Novel Feed

The chair of the joint working group reported on the experience with co-operation between the members and experts of the SCP, the SCAN and the SCF. The work was

progressing well, in particular the development of guidelines laying down the scientific background of the safety assessment of genetically modified organisms. The Committee noted that the differences in the regulatory background in the areas of release in the environment of GMOs and of novel foods would present a particular challenge.

7. Contaminants

7.1. Discussion on revision of the SCF opinion on dioxins on the basis of new information

The opinion prepared by the drafting group was adopted pending the inclusion of some editorial changes. The final text was adopted by written procedure. The full opinion appears as Annex I to these minutes.

7.2. Draft opinion on 3-Monochloro-propane-1,2-diol (3-MCPD) updating the SCF opinion of 1994

A revised draft of the opinion was presented during the meeting. The Committee considered that a threshold-based approach for deriving a TDI was appropriate and agreed on a TDI of 2 µg/kg bw in food. The final text was adopted after inclusion of editorial changes. The full opinion appears as Annex II to these minutes.

7.3. Draft opinion on T2-HT2 Toxin

After inclusion of minor editorial amendments the final opinion was adopted (see Annex III).

8. Food additives

8.1. Draft guidance on submissions for food additive evaluations by the Scientific Committee on Food

The Committee analysed the draft prepared by the Working Group on additives. The document is intended to update the current guidelines entitled “presentation of an application for assessment of a food additive prior to its authorisation” prepared by the Commission services in 1992 with contribution from the SCF and the member states authorities.

The drafts submitted to plenary represent a complex work with many different contributors drafting different sections covering the wide specialised expertise involved and a very heavy work of putting them together in a consistent and harmonised manner. The Committee welcomed the draft.

The Committee identified some issues that required further consideration in particular the sections regarding exposure, additives produced by microbiological products or derived from genetically modified organisms, that was not possible to resolve at the meeting itself. There were also a number of minor editorial changes identified.

The Committee also discussed a second document the annex providing further explanation on the requirements in the main guidelines and possible future developments in some of the areas. It was decided to include this document in the main guidance document as an annex.

The Secretariat also reported that the Commission Services prepared an administrative guidance intended to supplement the SCF guidelines on administrative questions (who to submit the dossiers, number of copies, format etc.).

The draft will be reworked for these questions and should enable a discussion with the view of adoption at the next plenary session.

8.2 Draft opinion on the safety of n-vinyl-2-pyrrolidone residues in polyvinylpyrrolidone and polyvinylpolypyrrolidone (insoluble polyvinylpyrrolidone) when used as food additives

The draft submitted by the Working Group on additives was discussed. A number of issues were discussed and resolved at the meeting. Subject to the changes agreed identified at the meeting the draft was considered adopted. The full opinion appears as Annex IV of these minutes.

8.3. Progress report on discussion on guidance on dossiers for safety evaluation of sources of nutrients or other ingredients proposed for use in the manufacture of foods

The Committee was presented with a draft working document specifying the progress on this issue. Contributions from the Working Groups on additives and nutrition had been received in this draft.

Substances of nutritional interest and other compounds can be used in the manufacture of dietetic foods in the existing directives and in food supplements and for food fortification purposes areas now being the object of harmonisation.

The Committee was developing the guidelines for this substances on the basis of its experience in its opinion on parnuts of May 1999 and taking into account the guidelines and the practice for other areas and in particular food additives.

The guidelines will require that administrative and technical data be submitted. As regards the administrative data the purpose of the request should be clearly indicated. The technical data will contain the sections to identify clearly the compound,

9. Flavourings

9.1 Discussion on issues related to the safety assessment of substances present in flavourings or other food ingredients with flavouring properties

The Committee discussed a note prepared by the Working Group on flavourings. During its discussions, the Working Group identified a number of general issues related to the exposure and risk assessment of particular flavourings that required a further discussion in the SCF plenary. Particular attention was given to the situation that some of the constituents to be dealt with are genotoxic and occur not only in flavourings, but also in

other food ingredients with flavouring properties (e.g. herbs and spices). On the request of the Commission representative from the legislative services, a discussion took place on the potential implications for implementation by legislators of the default conclusion of the SCF in such cases, i.e. that the exposure to genotoxic substances should be as low as possible. A strict application would not only result in the prohibition of certain flavourings but also of traditionally and commonly used herbs and spices. The Commission representative informed that a possible way might be that the exposure from herbs and spices is taken as the basis for establishing possible maximum limits. The Committee noted that any estimate of possible maximum levels would be hampered by the present lack of occurrence data of these substances in manufactured non-flavoured and flavoured foodstuffs and beverages. Conclusions on non-genotoxic substances for which toxicological concern exists have to be drawn on a case-by-case basis.

9.2. Draft opinion on estragol (1-Allyl-4 methoxybenzene)

A draft opinion was prepared by the flavourings Working Group and presented at the meeting. Based on the outcomes of the preceding discussion of the general issues with regard to the safety assessment of flavourings, the draft was deferred back to the working group for revision. The Committee agreed to rediscuss a revised draft opinion at the plenary meeting in September. In particular, information on the occurrence of the substance in natural source material should be included. After revision the document should serve as a model for opinions on other toxicological relevant substances present in flavourings and other food ingredients with flavouring properties. However, the Committee already expressed concern about the potential genotoxic properties of this substance.

9.3 Draft opinion on methyleugenol (4-Allyl-1,2-dimethoxybenzene)

Because of time limitations, the draft opinion on methyleugenol could not be discussed. However, based on the outcomes of the preceding discussion of the general issues with regard to the safety assessment of flavourings, the draft was deferred back to the working group for revision. The Committee agreed to rediscuss a revised draft opinion at the plenary meeting in September. Again, the Committee expressed concern about the potential genotoxic properties of this substance which acts very similar to estragole.

10. Upper Levels of Vitamins and Minerals

10.1. Tolerable Upper Intake Level for vitamin D

The rapporteur introduced the draft report discussed at the Task Force. The draft was very thorough and comprehensive. A discussion followed and some issues were identified. Unfortunately there was not sufficient time to resolve some of them at the meeting. It was decided therefore to address these issues as soon as possible in preparation either of the following plenary or the next one, taking into account the schedule of dates of meetings for the Task Force and the availability of the persons involved.

11. Nutrition/dietetic foods

Progress report

The item was postponed to the next meeting.

12. Food Contact Materials

12.1. Draft opinion on the 13th list of monomers and additives for contact materials

The draft evaluations submitted by the Working Group on food contact materials were considered by the Committee. The Committee agreed with the proposals for 17 substances from the Working Group pending some clarification in some cases. It also deferred the consideration of one substance included in the proposed list (PM/REF 13480, 2,2-Bis (4-hydroxyphenyl) propane, or bisphenol A) and requested the Working Group to consider the new substantial information that had become available recently. For three other substances the WG was asked to clarify the assessment carried out of the toxicological profile. The clarifications requested by the plenary at the previous meeting for two additional substances were now available and therefore the evaluations on these two substances were agreed by the Committee and included in the list adopted at this meeting. The full opinion appears as Annex V to these minutes.

12.2. Progress report

The item was postponed to the next meeting.

13. Novel Foods

13.1. Draft opinion on Salatrim

This item was withdrawn from the agenda.

14. Administrative issues relating to the rules of procedure of the SCF

Forms regarding the declarations of confidentiality, a practice done in all other sister Scientific Committees, were circulated for the members to sign.

14.1. Schedule of SCF meetings for 2001

The item was postponed to the next meeting.

15. Any other business

There was no other business.

ANNEXES

(The text of the opinions adopted in these annexes appear in the section outcome/opinions of the web pages of the SCF on the Internet, not in the section outcome/minutes).

ANNEX I

Opinion of the Scientific Committee on Food on Risk assessment of dioxins and dioxin-like PCBs - update based on new scientific information available since the adoption of the SCF opinion of 22nd November 2000. CS/CNTM/DIOXIN/20 final

ANNEX II

Opinion of the Scientific Committee on Food on 3-Monochloro-propane-1,2-diol (3-MCPD) - updating the SCF opinion of 1994. SCF/CS/CNTM/OTH/17 Final

ANNEX III

Opinion of the Scientific Committee on Food on Fusarium Toxins Part 5: T-2 Toxin and HT-2 Toxin. SCF/CS/CNTM/MYC/25 Rev 6 Final

ANNEX IV

Opinion of the Scientific Committee on Food on the safety of n-vinyl-2-pyrrolidone residues in polyvinylpyrrolidone and polyvinylpolypyrrolidone (insoluble polyvinylpyrrolidone) when used as food additives. SCF/CS/ADD/MsAd/198 Final

ANNEX V

Opinion of the Scientific Committee on Food on the 13th additional list of monomers and additives for food contact materials. SCF/CS/FCM/M85 final