



**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**

**SCF/CS/PLEN/MINS/135 rev.1**

**14 February 2003**

**Minutes of the 135<sup>th</sup> Plenary Meeting  
of the  
Scientific Committee on Food  
held on 2/3/4 December 2002 in Brussels**

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[http://europa.eu.int/comm/food/fs/sc/scf/index\\_en.html](http://europa.eu.int/comm/food/fs/sc/scf/index_en.html)

**Members/Membres/Mitglieder**

Mr. J. ALEXANDER  
 Mr. A. FLYNN  
 Mrs. S. BARLOW Vice Chair  
 Mr. A. CARERE (present on 3-4 December)  
 K-H. ENGEL  
 W. GRUNOW  
 T. HIRVI (present on 2-3 December)  
 Mrs. A. KNAAP Chair (present on 3-4 December)  
 Mr. J.C. LARSEN  
 S. LINDGREN  
 B. MOSELEY  
 A. PALOU  
 W. SARIS  
 J. SCHLATTER  
 P. TOBBACK  
 J.-M. WAL (present on 3-4 December)  
 R. WALKER

**Experts**

Mr. J.GRY (present on 3 December)

**Commission/Kommission**

Mr. A. KLEPSCH (DG Health and Consumer Protection)  
 Mrs. H. LEE " "  
 Mr. M. SLAYNE " "  
 Mr. L. ROSSI " "

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

Mr. M. A. GRANERO ROSELL  
 Mrs. T. SÄTERI  
 Mr. D. LIEM  
 Mrs. P. RODRIGUEZ IGLESIAS  
 Mrs. C. HEPPNER  
 Mr. T. HALLAS-MØLLER  
 Mrs. H. PEDERSEN

**1. Welcome, apologies for absence**

The First Vice Chairperson chaired the initial part of the meeting and welcomed the participants.

**- New staff in Secretariat**

The additional new staff referred to at the previous meeting were introduced. Dr. Claudia Heppner and Dr. Torben Hallas -Møller are working in the SCF scientific secretariat to help ensure the smooth transition to the EFSA in particular relating to the activities of the Panel on food additives, flavourings, processing aids and food contact materials. The Committee welcomed the new staff.

**- Apologies for absence**

Apologies for absence were received from B. Koletzko and P. Verger.

**2. Adoption of the agenda**

The agenda was adopted.

**3. Declarations of interest**

S. Barlow and R. Walker declared an interest on boron. The Committee considered that they could attend during the discussion of this item in the agenda as the discussion was only of a preliminary nature concerning how to coordinate the handling of the topic in the Additives and Nutrition Working Groups.

**4. Co-ordination with the Scientific Steering Committee and other Scientific Committees**

The ongoing activities of the SSC were briefly outlined.

**5. New requests for opinion**

**5.1 Request regarding purity criteria of Beta-carotene from *Blakeslea trispora***

The SCF adopted an opinion on 22 June 2000 (corrected on 7 September 2000) on the safety of beta-carotene from a dried biomass source, obtained from a fermentation process with *Blakeslea trispora* for use as a colouring matter for foodstuffs. The Commission Directive 2001/50/EC of 3 July 2001 amending Directive 95/42/EC laid down specific purity criteria concerning colours for use in foodstuffs following the

advice from the SCF opinion. These specify in the purity section the limits and type of solvent residues that are permissible for this product.

The Commission services have received a request from a petitioner to use other solvents than ethyl acetate and ethanol in the process of manufacturing beta-carotene from *Blakeslea trispora*. The Committee is therefore asked to evaluate the safety in use of the extraction solvents isopropyl alcohol and isobutyl acetate for the production of beta-carotene from *Blakeslea trispora*. . It was referred to the Additives Working Group.

## **6. Contaminants**

### **6.1 Polycyclic aromatic hydrocarbons (PAH) in food. Draft opinion**

The Committee acknowledged the impressive work by the Task Force on PAH and thanked the Task Force for all the work carried out. The Chairman of the Task Force introduced the key issues in the draft opinion, which had been changed based on discussions at the previous plenary meeting. The Committee discussed the new version of the document and agreed on a number of modifications. The draft opinion and the background document were adopted subject to incorporation of the changes proposed.

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

## **7. Flavourings**

### **7.1 Furfural and furfural diethylacetal. Draft opinion**

The draft opinion prepared by the Flavourings Working Group was introduced and discussed. The document was adopted subject to incorporation of minor changes as suggested during the discussion by the Committee.

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

### **7.2 Thujone. Draft opinion**

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 III** of these minutes.

### **7.3 Flavouring Group Evaluation FGE.01. Draft opinion**

The Committee discussed a revised draft of the first flavouring group evaluation as jointly prepared by the SCOOP working group on chemically defined flavouring substances and the SCF working group on flavourings. This flavouring group comprises 17 branched-chain aliphatic acyclic saturated aldehydes, carboxylic acids and esters derived from aliphatic acyclic primary saturated alcohols and branched-chain aliphatic acyclic saturated carboxylic acids. These 17 flavouring substances belong to chemical groups 1 and 2 of Annex I of Regulation (EC) No 1565/2000. 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 IV** of these minutes.

### **7.4 Flavouring Group Evaluation FGE.02. Draft opinion**

The Committee also discussed a draft of the second flavouring group evaluation as jointly prepared by the SCOOP working group on chemically defined flavouring substances and the SCF working group on flavourings. This group comprises 41 saturated alcohols, aldehydes and esters derived from aliphatic acyclic primary alcohols and linear aliphatic acyclic carboxylic acids. These 41 flavouring substances belong to chemical groups 1 and 2 of Annex I of Regulation (EC) No 1565/2000. 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 V** of these minutes.

## **8. Food additives**

### **8.1. Impurities of 1,4- dioxane, 2-chloroethanol and mono- and diethylene glycol in food additives**

The draft opinion prepared within the Additives Working Group was introduced and discussed. The document was adopted subject to incorporation of changes as suggested during the discussion by the Committee and cleared subsequently via the written procedure.

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

## **8.2. Aspartame. Re-evaluation on the basis of new data since the previous SCF evaluation**

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

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

## **9. Nutrient sources**

### **9.1. Boron sources in dietetic foods. Preliminary discussion**

The SCF received a request to evaluate the safety of a number of chemical substances for use in dietetic foods with nutritional purposes, following a request to the Commission services. Among these compounds there were boric acid and sodium borate. The Working Group on Additives was seeking advice from the Plenary in order to clarify the relationship with the on going exercise on the Tolerable Upper intake Levels of vitamins and minerals. This activity is being carried out by a specific SCF Task Force, and boron could be one of the minerals they have to consider. After the discussion, the Committee considered it appropriate to establish an effective co-ordination between the evaluation of an upper level for boron and the safety evaluation of boric acid and sodium borate so that the two working groups will be working closely in these two aspects. The upper level Task Force could start the discussion at their next meeting on the basis of the prepared paper.

## **10. Food Contact Materials**

### **10.1. Consideration of a Fat Consumption Factor (FRF) in the estimation of the exposure to a migrant from food contact materials. Opinion**

The Chairman of the Working Group Food Contact Materials introduced the draft opinion prepared by the Group. The Committee discussed the issue and agreed a number of changes to the draft.

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

### **10.2. Bisphenol A diglycidyl ether (BADGE).**

Following the considerations by the Working Group about the recent information available on this compound, the Committee discussed the issue and decided to prepare the following statement.

### Terms of reference

The Commission services asked the SCF to examine a) the new mutagenicity data available on BADGE.2HCl and b) to estimate the exposure of the consumer to BADGE and its derivatives regulated by Directive 2002/16/EC.

### Background

In its opinion of 24 March 1999 (1), the Scientific Committee on Food asked industry to provide within 3 years, detailed studies on BADGE and its chlorinated derivatives.

In July 2002 the Commission services and the SCF were informed that for BADGE the industry intends to transmit in February 2004 the results of a two-year gavage chronic toxicity/carcinogenicity study in the Fisher 344 rat. An intermediate report of this study describing the results obtained after the first 12 months is available.

The EC Commission services also received from the industry association in July 2002 (2) three mutagenicity studies on BADGE.2HCl, as requested previously by the Committee.

### Evaluation

The Committee examined the three mutagenicity studies on BADGE.2HCl supplied by the industry association along with two published reports and concluded as follows: *"The negative results obtained with BADGE.2HCl in the Ames test and a forward mutation assay in mammalian cells in vitro, indicate that BADGE.2HCl is unable to induce gene mutations in vitro. Negative results were also obtained in a well-conducted assay for structural chromosomal aberrations in vitro, indicating absence of clastogenic activity. Therefore, the positive response elicited by BADGE.2HCl in the in vitro micronucleus assay suggests that BADGE.2HCl might affect chromosome segregation, e.g. by interference with spindle organisation or function. This aspect should be further investigated, e.g. by testing BADGE.2HCl in the standard in vivo micronucleus test in the mouse (in bone marrow or peripheral blood erythrocytes)".*

The Committee carried out an assessment of exposure to BADGE and its derivatives regulated by Directive 2002/16/EC. The assessment was based on new surveys in the EU countries (3, 4, 5, 6, 7, 8) which found that migration levels into foods are considerably lower than in the past and are now well below the migration limit set in Directive 2002/16/EC (9). The Committee concluded that exposure of consumers (both average consumers and high consumers of food products expected to be in contact with can coatings that may contain BADGE) is low.

Taking into account the available toxicological database and the low exposure of consumers, and awaiting the results of the new mutagenicity test and of the ongoing two-year chronic toxicity/carcinogenicity study, the Committee can accept an extension to the deadline of its request for the detailed studies on BADGE and its chlorinated derivatives, until February 2004.

### References

- (1) SCF (Scientific Committee on Food), 1999. Opinion on Bisphenol A diglycidyl ether (BADGE), expressed on 24 March 1999. SCF/CS/PM 3243 Final. Available at [http://europa.eu.int/comm/food/fs/sc/scf/out28\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scf/out28_en.pdf)
- (2) Dossier submitted by APME (Association of Plastics Manufacturers in Europe).
- (3) JRC (Joint Research Centre), IHCP (Institute of Health and Consumer Protection, Ispra). Personal communication.
- (4) TNO Nutrition and Food Research. Personal communication.
- (5) Central Science Laboratory (UK). Personal communication.
- (6) Official Food Control Authority, Zurich. Personal communication
- (7) GEMS/FOOD Regional Diets, Regional Per Capita Consumption of Raw and Semi-processed Agricultural Commodities, WHO/FSF/FOS/98.3, WHO, Geneva, 1998.
- (8) SECODIP: Enquête National sur les achats des ménages, Paris, 1997.
- (9) Directive 2002/16/EC on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs, OJ L51, 22.02.2002 p.27-31

This statement also appears as **Annex IX** to these minutes.

### **10.3. Draft opinion on the 21<sup>st</sup> list of monomers and additives for food contact materials**

As there was not enough time to discuss this issue appropriately, it was decided to defer this issue to next meeting.

### **10.4. Consideration on certain trimethylhexane compounds (1,6-Diamino-2,2,4-trimethylhexane (PM/REF.N. 15370), 1,6-Diamino-2,4,4-trimethylhexane (PM/REF.N 15400) and on their mixture of (40% w/w) 1,6-diamino-2,2,4-trimethylhexane and (60% w/w)1,6-diamino-2,4,4-**



**trimethylhexane (PM/REF. N. 22331, previously mentioned as PM/REF.N. 15355)**

The Committee, on the basis of the considerations by the Working Group, decided to issue the following statement:

The Committee was asked to clarify the evaluations of the two chemicals and their mixture mentioned above.

These three were classified by SCF (SCF, 2001) into list 3 with the same restriction of 5 mg/kg of food.

The Committee noted that all the documentation available on these three refers only to the mixture and not to the individual substances. Therefore the Committee withdraws the previous evaluations of substances PM/REF.N. 15370 and 15400. Due to possibility of the variation of the % of the individual substances in the product, the Committee agrees to classify in list 3 the following mixture:

**Mixture of (35-45% w/w) 1,6-diamino-2,2,4-trimethylhexane and (55-65% w/w)1,6-diamino-2,4,4-trimethylhexane (PM/REF. N. 22331, previously mentioned as PM/REF.N. 15355)**

#### **References**

- SCF, 2001. Opinion of the Scientific Committee on Food on the 13th additional list of monomers and additives for food contact materials, (Adopted by the SCF on 30 May 2001). CS/PM/GEN/M85 Final. Available at [http://europa.eu.int/comm/food/fs/sc/scf/out86\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scf/out86_en.pdf)

This statement also appears as **Annex X**.

#### **10.5 Re-allocation of some substances for consistency with new SCF guidelines for food contact materials**

It had been noticed that for some substances, evaluated in the past by the Committee, the requested supplementary data were not in accordance with the current SCF guidelines. Without re-evaluating these substances, the Committee considered it

appropriate at present to change the lists of "needed studies" for these compounds to bring them in line with the prevailing guidelines.

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

## **11. Novel foods**

### **11.1. Draft opinion on Tahitian Noni juice**

The draft document prepared within the Novel Food Working Group was presented and discussed. The opinion 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.

### **11.2. Draft opinion on applications for approval of a variety of plant sterol-enriched foods**

The draft document prepared within the Novel Foods Working Group was introduced and discussed.

The Committee prepared the following statement:

“The Committee is currently considering a number of applications for the approval of novel foods-containing phytosterols and phytostanols and notes that regular consumption of a number of such products could result in intakes of phytosterols/phytostanols greater than the recommended range. The Committee agreed to have one opinion covering several applications for the approval of novel foods-containing phytosterols/phytostanols. During the discussions the Committee agreed on a number of modifications. The Working Group will meet again in January 2003 to discuss the modifications suggested and intends to submit a revised draft opinion to the next plenary meeting of the SCF.

The Committee recently concluded it prudent to avoid plant sterol intakes exceeding a range of 1-3 g/day (SCF, 2002). The Committee considers that approval of new products enriched with phytosterols/phytostanols would necessitate the development of appropriate risk management measures to minimise the risk of cumulative intakes from different type of products exceeding the range of 1-3 g/day.”

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

## **12. Tolerable Upper Intake Levels for Vitamins and Minerals**

### **12.1. Draft opinion on the tolerable upper intake level of Zinc**

As there was not enough time, the discussion of the draft opinion was deferred until the next plenary meeting of the Committee.

### **12.2. Draft Opinion on the tolerable upper intake level of Vitamin D**

The draft opinion prepared by the Working Group was examined by the Committee. The opinion was adopted subject to incorporation of changes as suggested during the discussion by the Committee.

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

## **13. Nutrition**

### **13.1. Progress report**

The Chair of the Working Group on Nutrition reported briefly about the on-going review of reference nutrient values for vitamins and minerals to be used for labelling purposes. This request had been made by the Commission service in February 2002 (see minutes of the 131<sup>st</sup> plenary meeting of the SCF). This exercise takes into account on the one hand recent scientific developments and also relevant data from Member States and similar values established by international bodies. A draft opinion on this issue is likely to be submitted to the Committee for its next plenary meeting.

## **14. General information by Commission services on matters relating to the SCF**

The Committee was informed in general about the progress in relation to the EFSA establishment, such as the appointment of its Executive Director and other on going steps in the full establishment of the EFSA.

## **15. Administrative information**

### **-Schedule of meetings in 2003**

The tentative schedule of meetings for 2003 was noted.

**16. Any other business**

There was no other business.

**17. Adoption of these minutes**

These minutes were adopted by written procedure on 14 February 2003.

## ANNEXES

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

### ANNEX I

- Opinion of the Scientific Committee on Food on the risks to human health of Polycyclic Aromatic Hydrocarbons in food. SCF/CS/CNTM/PAH/29 Final.
- ANNEX: Polycyclic Aromatic Hydrocarbons – Occurrence in foods, dietary exposure and health effects (Background document to the opinion of the Scientific Committee on Food on the risks to human health of polycyclic aromatic hydrocarbons in food expressed on 4 December 2003). SCF/CS/CNTM/PAH/29 ADD1 Final.

### ANNEX II

Opinion of the Scientific Committee on Food on furfural and furfural diethylacetal. SCF/CS/FLAV/FLAVOUR/11 ADD1 Final.

### ANNEX III

Opinion of the Scientific Committee on Food on thujone. SCF/CS/FLAV/FLAVOUR/23 ADD2 Final

### ANNEX IV

Opinion of the Scientific Committee on Food on chemically defined flavouring substances listed in the EU register Flavouring Group Evaluation 1 (FGE.01): Branched-chain aliphatic saturated aldehydes, carboxylic acids and related esters of primary alcohols and branched-chain carboxylic acids from chemical groups 1 and 2 (Commission Regulation (EC) No 1565/2000 of 8 July 2000). SCF/CS/FLAV/FLAVOUR/42 Final.

### ANNEX V

Opinion of the Scientific Committee on Food on chemically defined flavouring substances listed in the EU register Flavouring Group Evaluation 2 (FGE.02): Branched- and straight-chain aliphatic saturated primary alcohols, aldehydes and related esters of primary alcohols and straight-chain carboxylic acids from chemical groups 1 and 2 (Commission Regulation (EC) No 1565/2000 of 8 July 2000). SCF/CS/FLAV/FLAVOUR/44 Final.

### ANNEX VI

Opinion of the Scientific Committee on Food on Impurities of 1,4-dioxane, 2-chloroethanol and mono- and diethylene glycol in currently permitted food additives and in proposed use of ethyl hydroxyethyl cellulose in gluten-free bread. SCF/CS/ADD/EMU/198 Final

### ANNEX VII

Opinion of the Scientific Committee on Food: Update on the Safety of Aspartame. SCF/CS/ADD/EDUL/222 Final

#### ANNEX VIII

Opinion of the Scientific Committee on Food on the introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials. CS/PM/3998 Final

#### ANNEX IX

Statement of the Scientific Committee on Food on Bisphenol A diglycidyl ether (BADGE). SCF/CS/PM/GEN/13510/22112002 Final

#### ANNEX X

Statement of the Scientific Committee on Food on 1,6-Diamino-2,2,4-trimethylhexane (PM/REF.N. 15370), 1,6-Diamino-2,4,4-trimethylhexane (PM/REF.N 15400) and on their mixture of (40% w/w) 1,6-diamino-2,2,4-trimethylhexane and (60% w/w)1,6-diamino-2,4,4-trimethylhexane (PM/REF. N. 22331, previously mentioned as PM/REF.N. 15355). SCF/CS/PM/GEN/(15370-15400-22331) Final

#### ANNEX XI

Statement of the Scientific Committee on Food on the re-allocation of some substances for consistency with new SCF guidelines for food contact materials. CS/PM/4031 Final

#### ANNEX XII

Opinion of the Scientific Committee on Food on Tahitian Noni<sup>®</sup> juice. SCF/CS/NF/DOS/18 ADD 2 Final

#### ANNEX XIII

Minutes' statement of the Scientific Committee on Food on applications for approval of a variety of plant sterol-enriched foods. SCF/CS/NF/DOS/25 Final

#### ANNEX XIV

Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin D. SCF/CS/NUT/UPPLEV/38 Final