Minutes of the 120 th Meeting of the Scientific Committee on Food held on 8-9 March 2000 in Brussels

ATTENDANCE LIST / LISTE DES PARTICIPANTS / TEILNEHMERLISTE

Members/Membres/Mitglieder

Mme. S. Barlow, MM. A. Carere, D. Boskou, I. Elmadfa (2 nd Vice-Chairman, Vice-President, Stellv. Vorsitzender), Mme. A. Ferro-LuzziI, MM. A. Flynn, R. Fries (present on 8 March only), W. Grunow, Mme. A. Knaap (1 st Vice-Chairman, Vice-President, Stellv. Vorsitzende), MM. I. Knudsen (Chairman, President, Vorsitzender), S. Lindgren (present on 8 March only), B. Moseley, K-H. Nau, A. Palou, W. Saris, P. Tobback, P. Verger (present on 8 March only), R. Walker

Apologies/Excusés/Entschuldigt

MM. J.-M. Wal

Commission/Kommission

F. Verstraete (DG Health & Consumer Protection), MM. A. Klepsch (DG Health & Consumer Protection), G. Schreiber (DG Health & Consumer Protection), Mme S. Heinimaa (DG Health & Consumer Protection), Mme H. Hoffmann (DG Health & Consumer Protection)

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

MM. M. A. Granero Rosell, D. Pettauer, Mme. J. Thollebeke

1. Apologies for absence

The apologies for absence were noted.

2. Adoption of the agenda

The draft agenda was revised and adopted.

3. Declarations of interest

Prof. Walker declared an interest on item 9.4. He had made this declaration of interest already at the time of the discussions in the Working Group. He was member of the GRAS panel that had studied this substance in the US and this before becoming member of the SCF. The meeting acknowledged this interest and agreed that he could attend the discussion although not take part in the decision.

4. Matters arising from the minutes of the 119 th meeting

None.

5. Requests for new opinions

Novel Foods:

The Committee is asked to deliver its opinion on the safety of SALATRIMs as novel food.

Food Additives:

The Committee is asked to deliver an opinion on the safety in use of neotame as a sweetener and as flavour enhancer.

Flavourings:

Safety evaluation of a list of substances present in flavourings or other food ingredients with flavouring properties (active principles).

Food Microbiology and Hygiene:

- - Microbiological safety of fruits and vegetables eaten raw, and products thereof;
- - Evaluation of safety for human health of Bioprotein for animal feed use.

These new requests were noted.

6. Draft report on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen

The draft prepared by the Working Group was presented and discussed. During the discussion a number of issues were identified that required further detailed consideration This regarded among others, the safety aspects of some of the substances mentioned in the report. As these aspects required detailed consideration it was decided to consider these issues at working group level. The revised draft opinion will be submitted to the plenary session once these issues are resolved.

7. Contaminants

7.1. Statement on patulin

The Committee adopted the following text as prepared and presented by the rapporteur:

Patulin is a mycotoxin produced by fungi belonging to several genera, including *Penicillium, Aspergillus* and *Byssochlamys* species. Although patulin can occur in many mouldy fruits, grains and other foods, the major sources of patulin contamination are apples and apple products.

The Committee expressed an Opinion on patulin in 1994 in which it stated: "The Committee agrees for the time being with the JECFA and IARC conclusions. It proposes to reconsider its opinion in the light of new information." (SCF 1996).

The background for this opinion was (1) the JECFA evaluation of 1990 when a provisional tolerable weekly intake (PTWI) of 7 ug/kg bw was established, based on a no-effect level (NOEL) of 0.1 mg/kg bw/day in a combined reproductive toxicity/long term toxicity/carcinogenicity study in rats, and (2) the IARC conclusion that no evaluation could be made of the carcinogenicity of patulin to humans and that there is inadequate evidence in experimental animals (JECFA, 1990, IARC, 1986).

Patulin was reviewed by JECFA in 1995 and it appeared that, although several more studies were incorporated, the above mentioned study was still the most sensitive. Since it became apparent that patulin was administered only three times per week during 24 months, the NOEL in this study was recalculated to be 43ug/kg bw/day. As patulin does not accumulate in the body and in the light of the consumption pattern, the PTWI was changed to a provisional maximum tolerable daily intake (PMTDI). Based on a NOEL of 43 ug/kg bw/day and a safety factor of 100, a PMTDI of 0.4 ug/kg bw was established (JECFA, 1995).

A recent literature survey from 1995 onwards revealed many publications on patulin, dealing primarily with chemical analyses and in vitro studies and only a few with in vivo studies. However, none of these studies would change the assessment made by JECFA in 1995.

The Committee, therefore, endorses the PMTDI of 0.4 Î¼g/kg bw for patulin.

References

- - SCF 1996: Reports of the Scientific Committee for Food(Thirty-fifth series),1996
- - JECFA 1990: Evaluation of certain food additives and contaminants. WHO Technical Report Series,No.789,1990, and corrigenda
- - IARC 1986: IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans,Vol.40,1986
- - JECFA 1995: Evaluations of certain food additives and contaminants. WHO Technical Report Series, No.859,1995

8. Novel Food

8.1. Draft opinion on phytosterol esters

The draft opinion was presented by the rapporteur and discussed in detail by the Committee. Although no final agreement could be reached on how to address certain issues, the Committee felt that postponing of the discussion was not necessary, and asked the Secretariat to co-ordinate a written consultation with the Committee members to resolve the remaining issues. This procedure was concluded and the final text adopted on 6 April. The text of the opinion is attached as Annex I to these minutes.

8.2. Draft opinion on ngali nuts

The revised draft opinion was adopted. The final text of the opinion is attached as Annex II to these minutes.

The Committee was of the opinion that the dossier supplied in support of the case for marketing ngali nuts in Europe was clearly defective in addressing the requirements of the SCF Guidelines and the SCF is disappointed that it reached the Committee for a decision. The Committee hopes that similar cases where the information supplied by the petitioner is unlikely ever to satisfy the requirements for a safety assessment are not brought to it in the future.

8.3. Draft opinion on cereal brans as fat replacers

The draft opinion presented by the rapporteur was discussed in detail. The Committee felt that certain issues would require further clarification and asked the rapporteur to present an updated draft for the next meeting.

8.4. Discussion on SCF guidelines on novel foods and processes

The chairman of the Working Group on Novel Foods and Processes reported that the group had identified the need to revise the SCF Guidelines of 1997 on several aspects. However, the chairman pointed out that the capacity of the group would not allow it to embark on this activity in the short term, because it was totally occupied at present by the evaluation of individual dossiers.

9. Additives

9.1. Draft opinion on sucralose

The draft opinion was introduced by the Chair of the Working Group. The new draft addressed in more detail the issues discussed at the earlier plenary session. However, the Committee felt it was necessary to request additional information from the petitioner as the best manner to address the remaining issues.

9.2. Draft opinion on cyclamate

Cyclamate had been evaluated previously by the Committee for the last time in 1994. In that opinion the Committee had asked for a number of additional studies. The new information had now been submitted to the Committee.

The draft opinion was introduced and then discussed. After the discussion and subject to minor amendments the draft opinion was adopted.

The full opinion appears as Annex III to these minutes.

9.3. Draft opinion on acesulfame K

The Committee has examined new information on acesulfame K since its last evaluation. The draft opinion prepared by the working group on the basis of the new information was presented and discussed. After discussion and subject to the changes agreed the opinion was adopted.

The full opinion appears as Annex IV to these minutes.

9.4. Statement on acesulfame aspartame salt

The Committee considered a draft statement discussed at the Working Group on this salt. The Committee adopted it without changes. The statements is as follows:

The Committee is asked to deliver an opinion on the safety in use of aspartame-acesulfame salt as a sweetener. Aspartame and acesulfame K are approved additives in the EU. Purity criteria for aspartame and acesulfame K have been laid down by Commission Directive 95/31/EC. The aspartame-acesulfame salt is a real salt which, when added to foods (aqueous food and also in the mouth), dissociates into an anion (negatively charged acesulfame) and a cation (positively charged aspartame). These two ions are the same as those deriving from the two approved sweeteners. The difference is that the potassium cation of acesulfame K has been replaced by aspartame. The two molecules are combined in a fixed one to one ratio. The dissociation of the aspartame-acesulfame salt in an aqueous solution would be chemically expected but it is further confirmed by Nuclear Magnetic Resonance studies in simulated gastric juice. These studies demonstrate the release of the same ions as those deriving from an equimolar mechanical blend of aspartame and acesulfame K.

Considering that a) the salt represents an alternative source of aspartame and acesulfame ions to the two already permitted sources (E951 and E950), b) potential exposure is the same with an equivalent blend of aspartame and acesulfame K, c) the use of this substance raises no additional safety considerations the Committee regards as acceptable the use of aspartame-acesulfame salt as an additive.

It should be ensured that consumption of this substance is taken into account when estimating intakes of aspartame and acesulfame K in relation to the ADIs for these substances.

9.5. Statement on purity criteria of algal beta carotene from *Dunaliella salina*

Following the Committee's opinion on the safety of an algal beta-carotene preparation from *Dunaliella salina* as a food colour [1] , the Commission services have requested a further view regarding the use of edible oils as a replacement for soya bean oil as a carrier in the draft changes of specification that the Commission is envisaging following this advice of the Committee. The Committee has no objections to the use of edible vegetable oils as a replacement for soya bean oil as carrier for this algal beta carotene.

10. Upper levels for vitamins and minerals

10.1. Discussion and possible adoption of the opinion on upper level for folate

10.2. Discussion and possible adoption of the opinion on upper level for manganese

Both working documents prepared by the Task Force were discussed. In both cases there were a number of remaining issues that needed detailed consideration and therefore the two documents were sent back to the Task Force for clarification of the issues.

11. Food Contact Materials

Draft opinion on the ninth additional list of monomers and additives for food contact materials

Due to lack of time this draft could not be adopted and was postponed to next meeting.

12. Schedule of SCF meetings

Schedule for 2000 (final confirmation of dates)

Dates for the following meeting were confirmed as follows:

- 20 - 22 June, starting at 13.00 on 20 June;
- 6 - 7 September, starting at 10.00 on 6 September;
- 17 - 19 October, starting at 13.00 on 17 October.

13. General information from the Commission services

13.1. Additional information related to the 5 th Framework Research and Development Programme on matters relevant to the SCF

This information was distributed in writing to the members.

14. Progress reports from Working Groups

No detailed progress reports were made due to the lack of time. The provisional dates for the meetings of the working groups in 2000 are the following:

Working Group on Additives
3/4 May, 5/6 July, 27/28 September.

Working Group on Contaminants
5 May, 7 July, 29 September.

Working Group on Flavourings
17/18 July, 23/24 October.

Working Group on Food Contact Materials
10/11/12 May, 18/19/20 September, 27/28/29 November.

Working Group on Food Microbiology and Hygiene
23/24 March, 16 May, 3 July, 5 October.

Working Group on Novel Foods and Processes
15 May, 3/4 July, 4 October.

Working Group on Nutrition
14 June, 5 September, 13 December.

Task Force on Dioxin
13/14 March, 18/19 May.

Task Force on Upper Levels for Vitamins and Minerals
30/31 March, 23/24 May, 12/13 July.

Due to the renewal of the Committee in November 2000 no meetings have been scheduled yet for most of the working groups/task forces for November/December 2000.

15. Any other business

None.

16 .Adoption of these minutes

These minutes were adopted by written procedure.

ANNEXES

- ANNEX I: Opinion on a request for the safety assessment of the use of Phytosterol Esters in Yellow Fat Spreads
- ANNEX II: Opinion on the safety assessment of the nuts of the Ngali tree
- ANNEX III: Revised opinion on cyclamic acid and its sodium and calcium salts
- ANNEX IV: Opinion on the Re-evaluation of acesulfame K with reference to the previous SCF opinion of 1991

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[1] opinion on a request for the use of algal beta-carotene as a food colour, expressed on 13 June 1997, and statement clarifying certain aspects of this opinion included in the minutes of the 114th meeting of the Committee held on 9/10 December 1999