Minutes of the 117 th meeting of the Scientific Committee on Food - held on 16/17th June 1999 in Brussels

ATTENDANCE LIST/LISTE DES PARTICIPANTS/TEILNEHMERLISTE

Members/Membres/Mitglieder

Mme. S. BARLOW, MM. D. BOSKOU, A. CARERE, I. ELMADFA (2 nd Vice-Chairman, Vice-President, Stellv. Vorsitzender), Mme. A. FERRO-LUZZI, MM. A. FLYNN, R. FRIES, K-H. NAU, Mme. A. KNAAP (1 st Vice-Chairman, Vice-President, Stellv. Vorsitzender), MM. I. KNUDSEN (Chairman, President, Vorsitzender), S. LINDGREN, B. MOSELEY, A. PALOU, P. TOBBACK, J.-M. WAL, R. WALKER

Apologies/Excusés/Entschuldigt

M. W. SARIS, M. W. GRUNOW

Experts

J.C. LARSEN, J. STARTIN, P. FŰRST

Commission/Kommission

MM. A. KLEPSCH (DG III/E/1), O. ROHTE (DG III/E/1), B. MATHIOUDAKIS (DG III/E/1), L. ROSSI (DG III/E/1)
M. MISCHENDAHL (DG III/E/2)
P. DASKALEROS (DGXXIV)

Secretariat/Secrétariat/Sekretariat

MM. M. A. GRANERO ROSELL (DG XXIV/B/3), D. PETTAUER (DG XXIV/B/3), Mme. J. THOLLEBEKE (DG XXIV/B/3)

1. Apologies for absence

The apologies for absence were noted.

2. Welcome to the new members

The two new appointed members of the Committee [1], Dr. Nau and Dr. Walker were welcomed by the other members of the Committee.

3. Adoption of the agenda

The agenda was adopted adjusting appropriately the order of the items.

4. Declarations of interest

No interests were declared.

5. Urgent question: dioxins in foods

The Committee was asked as a matter of urgency to advise the Commission whether, on the basis of consumer health considerations, there are grounds to treat milk and milk products (with the exception of butter) differently from other products specified in Article 1 (1.A) of Commission Decision 1999/368/EC. The Committee adopted its final opinion on the basis of a draft document prepared by an ad hoc working group, which was convened the previous day. Participants at the meeting of the ad hoc working group were members of the SCF and Dr. J. Livesey, Dr. Di Domenico, Dr. P. Fürst, Dr. J. C. Larsen, Dr. J. Startin as invited experts.

The full opinion adopted by the Committee appears as Annex I to these minutes.

6. Matters arising from the minutes of the 116 th meeting

- Adoption of minutes of 116 th meeting
- Follow-up on opinion on substances for nutritional purposes which have been proposed for use in the manufacture of foods for particular nutritional purposes ('parnuts')

- The Committee adopted the minutes of the previous 116 th meeting.

  As regards the opinion on substances for nutritional purposes which have been proposed for use in the manufacture of foods for particular nutritional purposes ('parnuts'), once the additional information requested by the Committee regarding the dipeptides tripeptides and oligopeptides had been submitted the Committee would reconsider this issue.

7. Requests for opinions

- nitrate (contaminant)
- fusarium toxins (contaminant)
- phytosterol esters in yellow fat spreads (novel food)
- green hearted chicory (novel food)
- Radicchio rosso (novel food)
- evaluation programme for chemically identified flavouring substances
- cyclamate (food additive)
- aspartame acesulfame salt (food additive)
- acesulfame K (food additive)

These new requests were noted.

8. Additives

- Stevioside as a sweetener

- The Committee considered the draft prepared by the Working Group. A number of comments were made and as a result a number of changes were introduced.

  The full opinion is given as Annex II to these minutes.

- Progress report from the Working Group

- **Hydrogenated poly-1-decene**

  Hydrogenated poly-1-decene has been previously authorised as a food additive in one Member State. An application has been made for EU wide authorisation to the Commission. The Committee has requested further information from the petitioner and will re-examine hydrogenated poly-1-decene when that further information has been provided.

9. Novel Foods

- Discussion and possible adoption of a draft opinion concerning a list of products which do not require labelling as they do not contain detectable traces of DNA or protein (Implementation of Regulation 1139/98 on labelling of novel foods)

- The Committee adopted the opinion on this item already discussed at the previous plenary session when it did not finalise the discussion. It clarified that, when addressing soy oil and maize starch specifically, it intended also to give guidance of a more general nature to be applied when the question of absence/presence of protein and/or DNA in food products of any kind is addressed outside the Scientific Committee on Food in the future. The Committee emphasised that the questions related to the "negative list" were of an analytical nature, addressing labelling issues rather than health concerns.

  The full opinion appears as Annex III to these minutes.

- Discussion and possible adoption of a draft opinion on phospholipids in egg yolk

- The Committee discussed and adopted the draft opinion prepared by the working group.

  The full text of the opinion that is attached as Annex IV.

- Discussion and possible adoption of a draft opinion on *Stevia Rebaudiana* Bertoni plants and leaves

- The Committee discussed and adopted the draft opinion prepared by the working group.

The full text of the opinion that is attached as Annex V.

- Progress report from the Working Group

- The chairman of the working group informed the Committee that an increasing number of dossiers in application of Article 11 of Regulation (EC) 258/97 (obligatory consultation of the SCF on matters relating to public health) can be expected for the near future. During the evaluation of the dossiers, the working group would, whenever relevant, co-operate closely with the Scientific Committee on Plants and take account of the comments submitted by the member states' authorities under the consultation procedure of Regulation (EC) 258/97.

  The working group envisages a review of the SCF guidelines on novel foods [2], considering in particular the issues of substantial equivalence, assessment of viable genetically modified micro-organisms in food and post-marketing surveillance.

  Working group meetings were scheduled for 26 July and 19 November 1999.

10. Nutrition

- Progress report from the Working Group

- The Working Group was progressing on its preparation of the report on the essential requirements for foods for sportsmen. The next meeting of the Working Group is scheduled for 21 September.

11. Upper levels of vitamins and minerals

- Discussion on criteria to be used

- progress report from the Task Force

- The Committee discussed the report from the Task Force and a number of points were raised for consideration by the Task Force. There was general approval for the approach to setting upper levels of vitamins and minerals proposed in the report.

  While discussing the issue, the beneficial and prejudicial effects of the addition of vitamins and minerals to food were raised by some members.

12. Food Hygiene and Microbiology

- Discussion and possible adoption of a report on criteria for safety evaluations for additives produced by microbiological processes

- The draft report was discussed. As there were a number of issues that required substantial clarification, it was decided that the Working Group would elucidate them.

13. Food Contact Materials

- Draft opinion on an additional list of monomers and additives for food contact materials

- The Committee considered a number of substances on which the Working Group had prepared a report to the plenary. The final list containing the substances on which the Committee could deliver its assessment in this occasion appears as Annex VI to these minutes.

  The Committee was informed also that the Standing Committee on Foods, the regulatory Committee composed by representatives of the Member States assisting the Commission, had adopted by unanimity the proposal for the 5 th amendment of Directive 90/128 on plastics. This 5 th amendment harmonises the legal status of 117 substances, which had been previously evaluated by the SCF.

14. Contaminants

- Gelatine: use of chromium tanned hides, discussion and possible adoption of opinion

- **Interim statement on chromium and the use of chromium tanned hides for gelatine production in relation to the request for the opinion of the SCF on the adequacy of a proposed specification for gelatine in terms of protection of consumer health**

  The Committee discussed in depth an interim statement on chromium from chromium tanned hides intended to be used to manufacture gelatine for human consumption. This interim statement only covers one aspect of the Commission's request for opinion of the Committee on the adequacy of a proposed specification for gelatine in terms of protection of consumer health. The other aspects relate to microbiological specifications and other chemical parameters for impurities which the Committee is considering and on which it give an opinion later. Several members expressed concern about other possible microbial and chemical health aspects of the chromium tanned hides since they are not covered by the hygienic practice normally applied to animal products intended for use in the human food supply. They were questioning the overall impact of the tanning procedure on human health aspects of gelatine apart from the use of chromium.

  The Committee has been informed that the only difference between the use of untanned hides and chromium tanned hides in gelatine production is in the additional application of chromium in the form of trivalent chromium(III). In addressing this question, the Committee has therefore only considered the issue of chromium III.

  The Committee has not been provided with any definitive data on the consumption levels of gelatine in EU countries. The Committee therefore made a rough estimate of possible maximum daily consumption of gelatine, using a «worst case» assumption that l.5 kg of food per day is consumed and that this contains 3% by weight of gelatine. If chromium III was present at the proposed limit of l0ppm in all gelatine consumed, then the daily intake of chromium III from this source would not exceed 450 µg/person/day, equivalent to 7.5 µg/kg b.w./day for a 60 kg person.

In considering the safety aspects, the Committee noted that the form of chromium used was Chromium III and not the known toxic form, chromium VI. The Committee also noted that the absorption of chromium III is low, around 0.5 - 2% if given orally. In a recent comprehensive review of the toxicity of chromium the US Environmental Protection Agency (EPA) has proposed a reference dose for CrIII of l.5 mg/kg b.w./day (i.e. an estimate of a daily exposure that is likely to be without an appreciable risk of deleterious effects during a lifetime). According to the EPA report, this was based on NOELs of around l400 mg CrIII/kg/day, taken from a 2-year oral chronic toxicity/carcinogenicity study in the rat and from a 90-day oral rat study, in both of which no adverse effects were observed from feeding CrIII, as Cr_2O_3, at levels up to 5% in the diet. The reference dose of l.5mg/kg/day was derived by application of a l000-fold safety factor to the NOEL. A factor of l000 rather than l00 was used because of uncertainties regarding potential reproductive effects of chromium III. Neither the SCF nor JECFA have established tolerable daily intakes for chromium.

As the «worst case» estimate of intake from gelatine containing CrIII at l0ppm is 200-fold lower than the EPA reference dose, the Committee does not consider that the proposed specification limit of l0ppm for chromium would pose any risk to consumer health, provided that the specification was restricted to the trivalent form of chromium and provided the assumptions the Committee has made about maximum likely intakes of gelatine covers the situation for EU consumers.

In relation to nutritional requirements for chromium, the Committee notes that there is currently no EU Population Reference Intake (PRI) for chromium but that the US Food and Drug Administration has selected a Reference Daily Intake for chromium of l20 µg/day. The Committee notes that the «worst case» estimate of intake from consumption of gelatine is higher than this US Reference Daily Intake value but that such values are set for nutritional purposes and do not give any indication of the upper level of intake which might be considered safe from a toxicological point of view. The Committee also notes that its «worst case» estimate of intake from consumption of gelatine is 450 µg/person/day compared with estimates from various countries of the average daily intake of chromium from all sources in the diet, which range between 22 and 250 µg/person/day.

The Committee is currently considering upper limits for vitamins and minerals in foods in general and may wish to return to the specific issue of gelatine specifications for chromium III, should that review indicate there is a need to do so. The Committee also wishes to point out that this interim advice on chromium III may need to be revised in the light of the Committee`s later advice on any overall limit for heavy metals in gelatine.

In the context of efforts to reduce levels of contaminants in the diet generally, the Committee emphasises the importance of good manufacturing practices and note that some sectors of industry have stated that they could comply with a lower standard for chromium III (e.g. l ppm).

Bibliographic references will be brought in the final opinion when adopted.

- progress report from the Working Group

- Due to lack of time it was not possible to report on this activity.

15. Flavourings

- progress report of the Task Force

- Due to lack of time it was not possible to report on this activity.

16. Review of the SCF 1998-2000Working Programme

This item could not be discussed and was deferred to the next meeting.

17. Review of schedule of SCF meetings for 1999

The secretariat distributed the latest version of the schedule of meetings.

18. SCF - Organisational matters

- SCF information pack (updated)

- The secretariat distributed an updated version of the information pack.

19. General information from the Commission service

This item was postponed due to lack of time

20. Any other business

There were no additional items to be discussed.

21. Adoption of these minutes

These minutes were adopted at the 118 th plenary session of the SCF on the 22 nd - 23 rd September 1999.

ANNEXES

ANNEX I: **Opinion on Dioxins in milk derived from cattle fed on contaminated feed in Belgium**
ANNEX II: **Opinion on stevioside as a sweetener**
ANNEX III: **Opinion concerning the scientific basis for determining whether food products, derived from genetically modified soya and from genetically modified maize, could be included in a list of food products which do not require labelling because they do not contain (detectable) traces of DNA or protein**
ANNEX IV:**Opinion on the safety assessment of phospholipids obtained from egg yolk as food produced using a new process**

ANNEX V: **Opinion on Stevia Rebaudiana Bertoni plants and leaves**
ANNEX VI: **Opinion on an additional list of monomers and additives for food contact materials**

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[1] **Official Journal No. C 152, 1/6/99**

[2] **Published as Commission Recommendation 97/618/EC of 29 July 1998 concerning the scientific aspects and the presentation of information necessary to support application for placing on the market of novel foods and novel food ingredients and the preparation of the initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council. Official Journal No L253, September 16, 1997.**