Minutes of the 110 th Meeting held on 14 -15 th January 1998 in Brussels

ATTENDANCE LIST - LISTE DES PARTICIPANTS - TEILNEHMERLISTE

Members/Membres/Mitglieder

- Mme. S. BARLOW
- MM. D. BOSKOU,
- A. CARERE,
- I. ELMADFA (Vice-Chairman, Vice-President, Stellv. Vorsitzender)
- Mme. A. FERRO-LUZZI
- MM. A. FLYNN, R. FRIES, W. GRUNOW
- Mme. A. KNAAP (Vice-Chairman, Vice-President, Stellv. Vorsitzender)
- MM. I. KNUDSEN (Chairman, President, Vorsitzender) *****,
- S. LINDGREN,
- B. MOSELEY,
- A. PALOU,
- W. SARIS,
- P. TOBBACK,
- P. VERGER,
- J.-M. WAL

Apologies/Excusés/Entschuldigt

- none

Others/Autres/Andere

- Mr. G. MERLINI (part of Item 6 of the agenda)

Commission/Kommission

- Mme. S. VAN DE LOUW (DG XXIV/B/2)
- MM. B. MATHIOUDAKIS (DG III/E/1),
- L. ROSSI (DG III/E/1)
- Mme. S. HEINIMAA (DG III/E/1)
- Mr. MIESCHENDAHL (DG III/E/2)

Secretariat/Secrétariat/Sekretariat

- Mr. P. J. WAGSTAFFE (DG XXIV/B.2)
- Mr. A. MARTIN MAGONE (DG XXIV/B.2)
- Mme. P. DECAMPS (DG XXIV/B.2)

1. Adoption of the agenda

The draft agenda was adopted

2. Apologies for absence

None

3. Declarations of interest

None

4. Matters arising from the minutes of the 108/109th meeting

First and second vice-chairmen

The Secretariat explained that after the Committee had elected Dr Knaap and Prof. Elmadfa as vice-chairmen at the 109th meeting of 11 November 1997, the Commission Services had requested all the scientific committees to designate first and second vice-chairmen. After extensive discussion of the criteria that would determine such a choice, it was agreed that Dr Knaap would be the first and Prof. Elmadfa the second vice-chairman.

No specific questions were raised concerning the minutes of the previous meetings.

In response to questions from Members, the Secretariat confirmed that, in accordance with Commision Decision 97/759 of 23 July 1997 establishing the scientific committees, the formal title of the SCF is now the Scientific Committee on Food.

5. Actions following from opinions and recommendations; General information from the Secretariat

The Secretariat reported that the Committee's recent opinion on certain additives for use in foods for infants and young children in good health and in foods for special medical purposes for infants and young children had been fundamental to recent discussions on the revision of the miscellaneous additives directive in the EP. Likewise, its opinion on a maximum residue limit (MRL) of 0.01 mg/kg for pesticides in foods intended for infants and young children had been central to discussions on this issue within the Commission. The Secretariat reported that the Committee's opinion on maximum levels for vitamins and minerals in baby foods had served as the basis for a draft directive modifying directive 96/5/EC which introduced maximum levels for vitamins and minerals in these products. The draft had received the favorable opinion of the Standing Committee for Foodstuffs and has now been notified to the World Trade Organisation before adoption by the Commission.

6. SCF - Organisational matters

SCF Information pack

The Secretariat introduced a revised information package which provided essential information on the scope, responsibilities and organisation of the SCF and now included a complete list of previous opinions. The pack provided information for new Members, the public and could also serve as a basis for presentations on the work of the Committee.

Working Programme for 1998

Deferred to discussion of the individual working groups.

Rules of Procedure for the SCF

The Secretariat introduced the draft rules of procedure and explained that, in accordance with the Commission Decision 97/579/EC setting up the scientific committees, each committee was required to adopt its own rules of procedure to ensure that it complied with the basic requirements of excellence, transparency and independence whilst respecting requests for confidentiality. It was logical that the rules of procedure of the individual committees should not diverge unnecessarily and that they were consistent as concerns certain fundamental principles. The Commission services had therefore drawn up an initial draft to serve as a basis for discussion. After general discussion, it was agreed that the Secretariat, in close collaboration with the Chairman and vice-chairmen, would collate the comments of Members for discussion at the next Plenary meeting.

WGs: Chairmen and Composition

Members reviewed the needs for continuation of the working group on intake and exposure. Given that exposure assessment is an essential component of risk evaluation, the working group should continue to explore approaches that would underpin the work of the other working groups. The Committee agreed the chairmen of the working groups as follows:

Working Group	**Chairman**
Additives	Dr S Barlow
Contaminants	Prof. A Carere
Materials in Contact with Food	Dr A Knaap
Novel Foods and Novel Processes	Dr B Moseley
Hygiene and Microbiology	Prof. S Lindgren
Nutrition and dietetic foods	Prof. I Elmadfa
Intake and Exposure	Dr Ph. Verger

The distribution of Members in the Working Groups was also agreed although it was stressed that this could be revised as necessary. It was agreed that the Secretariat would circulate the draft agendas of working groups to all Members. It was also agreed to continue to invite the *ad hoc* experts who were actively involved in on-going evaluations to working group meetings.

It was agreed that the activity on chemically defined flavouring substances should be organised initially as a task force for the first phase of its work which involved a review of the guidelines for evaluation of these substances.

Plenary and WG Meeting dates for 1998

The meeting dates for Plenary and most working groups were provisionally agreed.

The dates of the Plenary sessions are as follows:

Meeting	**Dates**
110th meeting	14/15 January
111th meeting	18/19 March

112th meeting	3 / 4 June
113th meeting	16/17 September
114th meeting	9/10 December

Presentation on the use of e-mail for Committees by the "EM4AG" project

M Merlini presented the Commission (DG III) funded project "E-mail for Administrative groups (EM4AG)" which had been set up to facilitate the use of e-mail for the transfer of documents between the Commission secretariats and members of Commission committees. M Merlini stressed the potential of e-mail in terms of speed and efficiency for the transfer of documentation and explained that the AM4AG project included technical assistance for Member State administrations where difficulties in inter-operability of e-mail systems were encountered. It was agreed to begin with an examination of e-mail addresses and to make trials with simple documents to identify the difficulties to be resolved. The Secretariat stressed that the introduction of electronic systems for use by Committee members was becoming increasingly important given the volume of documentation and the limitations of secretarial support.

7. Requests for opinions

The Committee was presented with the following requests for opinions from the Commission:

- - ß -cyclodextrin (food additive)
- - Imazalil (food additive -surface treatment agent)
- - lindane in baby foods: urgent request to follow up the Committees minute statement from its 109 th meeting (see item 15).
- - dietary copper with particular reference to calf liver (see item 10)

8. Risk analysis: Principles and terminology

The Chairman introduced the topic on the basis of the SCF opinion on principles for the development of risk assessment of microbiological hazards (13 June 1997) and the report of the Joint FAO/WHO consultation on Risk Management and Food Safety (Rome, 27 -31 January 1997) - FAO Food & Nutrition Paper 65.

The purpose of the presentation was to further promote the use of CODEX risk analysis principles and terminology in the work of the SCF. This was particularly important given the fact the Commission would increasingly rely on the advice of its scientific committees to defend the position of the Community in the WTO especially when it was not in line with the recommendations of CODEX advisory bodies. The FAO paper highlighted the need for risk managers to establish a risk assessment policy which would set out the boundaries for the work of the risk evaluators. Whilst recognising that a risk assessment policy was the responsibility of the risk manager, setting the policy would require input from the scientific committee.

Following a wide ranging debate, the Committee requested the Secretariat to explore within the Commission Services the question of establishing a risk assessment policy and how this could be approached.

9. Applicability of the ADI to infants

Discussion was deferred to the next meeting.

10. Nutrition and Dietetic Foods

Beta-carotene - high dose studies

The Rapporteur presented the revised report on the effects of ß-carotene supplementation in combination with tocopherol in clinical and chemo-preventive trials. It was recalled that the question from the Commission had been put as a consequence of reports that the use of ß-carotene supplementation in a trial involving Finnish smokers had led to an increase in the incidence of lung cancer amongst the treated group. The Commission had requested the Committee to advise it on any implications of these observations for dietary exposure to ß-carotene. Members congratulated the Rapporteur on the report which provided a detailed review of recent clinical trials and intervention studies. After extensive discussion it was agreed to add the terms of reference and to revise the conclusions.

The draft opinion would be submitted for adoption at the March 98 Plenary meeting.

Dietary copper with particular reference to calf liver

The Secretariat explained that the question has arisen from a request from the German authorities for the Commission to examine potential risk to public health resulting from the presence of high levels of copper in calf liver. The origin of the copper appears to be linked to the addition of the element to animal feed. The DG III representative noted that, since copper is considered to be essential nutrient and not a contaminant in food, this question should be examined in the broader context of current discussions relating to the addition of vitamins and minerals to foodstuffs. Members recognised that this raised the general question of assessing the upper safe limits for substances that were essential nutrients and that it would require input from toxicologists and nutritionists. Members requested more information on the occurrence of copper in liver in general, the extent of the problem in other Member States and the levels of consumption of calf liver by different population groups. It was agreed that the background information supplied by the German authorities would be circulated to the whole Committee. Two Members undertook to study the information from a nutritional and a toxicological point of view.

The matter would be discussed further at the next Plenary meeting.

11. Food Additives

Cross linked carboxymethyl cellulose

The Chairman of the Working Group introduced the draft opinion and explained that the evaluation concerned a request for the extension of use of cross linked carboxymethyl cellulose as a disintergrant in sweetener tablets to allow its use as a disintergrant in solid dietary supplements. The Commission services had asked for an accelerated procedure to resolve a legislative problem and the draft opinion had therefore been submitted to the Additives working group for comment by a written procedure and then to the Plenary.

The Committee concluded as follows:

The Committee has taken account of the previous and newly provided technical and toxicological information on cross-linked sodium carboxymethyl cellulose. It notes the lack of toxicity and long history of safe use of the parent compound, sodium carboxymethyl cellulose. The parent compound is known to be poorly absorbed, if at all, in animals and man, and it is likely that cross-linking reduces absorption even further. The Committee therefore recommends that the extension of use of cross-linked sodium carboxymethyl cellulose as a disintegrant in dietary supplements at a level not exceeding 30g/kg is acceptable.

The full opinion is given in Annex I.

12. Materials and Articles in Contact with Food

No matters were raised

13. Flavours

Discussion was deferred to the next meeting.

Novel Foods and processes (including irradiated food)

Report on developments with the evaluation of GM products in the framework of Directive 90/220/EEC by the Scientific Committee on Plants

The Chairman explained that the Scientific Steering Committee had been consulted by the Commission about the evaluation of the 4 genetically modified plants and had recommended that the Scientific Committee for Plants should take the lead and that a working group should be established involving Members of the SCP (Plant), SCF (Food), SCAN (Feed) and SCTEE (Toxicology/Ecotoxicology/Environment). The question was of high urgency and the Plant Committee had been requested to arrange for delivery of an opinion as soon as possible. The Rapporteur explained that the dossiers covered two applications for the marketing of seed for growing and two for plants intended for food/feed processing. Large dossiers on the 4 products had been distributed to the members of the working group. The Rapporteur had attended a first meeting on 22 December 1997 where it had been decided to examine the dossiers from the view points of biotechnology, toxicology and herbicide residues, environmental aspects and food/feed. The working procedure and time-table for evaluation had also been agreed. The Rapporteur had completed his assessment of substantial equivalence with the non-modified plants shortly before the present meeting. This had been sent simultaneously to the co-ordinator for the Plants Committee and to the SCF Secretariat who had transmitted it to Members.

Members were unclear about the responsibility of the SCF in this evaluation particularly as concerns novel food aspects and were concerned that there was too little time for the Committee to reach a view. The Secretariat explained that these applications had been made in the context of Directive 90/220/EEC prior to the entry into force of the Novel Food Regulations which included the mandatory consultation of the SCF on proposals for measures relating to public health. Although no question had been put formally to the SCF in the context of the novel foods regulation, it was important for the Committee to closely follow developments in this area. This was consistent with the Commission's stated policy of consulting its scientific committees on matters of public health independently of the need for obligatory consultation.

Members were concerned that substantial equivalence was increasingly interpreted in different ways and considered there was an urgent need for the Committee to examine this aspect in detail in the its Novel Foods Working Group.

Members considered that it was very important for the SCF to be fully involved in evaluations that had implications for food safety as such matters were its main responsibility. Otherwise, it would find it difficult to handle any supplementary questions on these dossiers should they arise.

The Committee requested the Chairman to ask the Scientific Steering Committee to clarify the role of the SCF in evaluation of such products with an intended food use and the division of scientific responsibilities between it and the Plant Committee.

14. Evaluation of safety of irradiated foods

Discussion was deferred to the next meeting

15. Contaminants

Lindane in baby foods

The Secretariat recalled that, at its 109 th meeting on 11 th November 1997, it had been informed verbally that the JMPR had recently reviewed the ADI and had reduced it substantially. In the light of this information and without knowing the reasons which led JMPR to reduce the ADI, the Committee concluded at that time that, as a matter of prudence, its earlier opinion could no longer be assumed to be valid. The Committee stated that it lacked the information to allow it to advise on an upper residue level for lindane in baby food.

In order to resolve a question concerning the free movement of baby food containing traces of lindane, the Commission has now requested the Committee for its urgent advice concerning a maximum level of lindane in foods intended for infants and young children that could be considered to be acceptable from the public health point of view.

The Committee undertook the assessment on the basis of the recent JMPR evaluation and the estimation of consumption of foods by infants and young children as described in its opinion "A maximum residue limit (MRL) of 0.01 mg/kg for pesticides in foods intended for infants and young children" expressed on 19 September 1997.

The Committee concluded as follows:

The Committee has previously only considered those pesticides which may be used as food additives. Thus lindane has never been evaluated toxicologically by the SCF.

The Committee was aware, however, that the FAO/WHO Joint Meeting on Pesticide Residues had recently (JMPR meeting of 22 September -1 October 1997) reviewed the ADI for lindane and had allocated a temporary ADI of 0 - 0.001 mg/kg b.w.. The toxicological evaluation, which was the basis for the temporary ADI, is in print and will be available in the near future from FAO/WHO.

In the Committee's opinion on "A maximum residue limit (MRL) of 0.01 mg/kg for pesticides in foods intended for infants and young children" expressed on 19 September 1997, a worst case intake of food for 12 month old infants was estimated to be 48 g/kg b.w./day

The temporary ADI, as set by JMPR, would not be exceeded by infants and young children consuming commercial products at the highest recorded 95 percentile every day i.e. 48 g/kg b.w., if lindane was present in all of these products at a maximum level of 0.02 mg/kg food.

The Committee now concludes therefore that a maximum level of lindane of 0.02 mg/kg in foods intended for infants and young children, could be considered to be acceptable from the public health point of view.

The full opinion is given in Annex II

16. Food Microbiology and Hygiene

Discussion was deferred to the next meeting.

17. Intake and Exposure

No matters were raised

18. Scientific Co-operation

M Rohte (DG III/E/1) presented an overview of the work of scientific co-operation (Directive 93/5/EC) with particular emphasis on tasks undertaken in support of the SCF. It was agreed that Members would be sent reports on recently completed tasks.

19. Any other business

No matters were raised