# Minutes of the 107th Meeting of the Scientific Committee for Food held on 12-13 June 1997 in Brussels

## ATTENDANCE LIST - LISTE DES PARTICIPANTS - TEILNEHMERLISTE

### Members/Membres/Mitglieder

- MME. S. BARLOW
- MM. D. BOSKOU
- J. A. AMORIM CRUZ
- A. CARERE
- I. ELMADFA
- MME. A. FERRO-LUZZI (Vice-Chairman, Vice-President, Stellv. Vorsitzender)
- MM. W. HAMMES
- A. HUYGHEBAERT
- MME. A. KNAAP
- MM. I. KNUDSEN (Vice-Chairman, Vice-President, Stellv. Vorsitzender)
- J. T. KUMPULAINEN
- G. PASCAL (Chairman, President, Vorsitzender)
- J. REY
- A. SOMOGYI

### EFTA/EEA Observer

- M. J. ALEXANDER (EFTA/EEA Observer)

### Others/Autres/Andere

- -

### Commission/Kommission

- MM. B. CARSIN (DG XXIV/B)
- W. PENNING (DG XXIV)
- H. BELVEZE (DG XXIV)
- MME. S HEINIMAA (DG III/E/1)
- MME. C. MAJEWSKI (DG III/E/1)
- MM. O. ROHTE (DG III/E/1)
- L. ROSSI (DG III/E/1)

### Secretariat/Serétariat/Sekretariat

- M. P. J. WAGSTAFFE (DG XXIV/B.2)
- MLLE. S. VAN IMPE (DG XXIV/B.2)

### Apologies/Excusés/Entschuldigt

- MM. P. J. AGGETT
- M. GIBNEY
- MME. O. TELLO ANCHUELA
- MM. S. LINDGREN
- C. NOMBELA CANO
- R. WENNIG
-

# 1. Adoption of the agenda

The agenda was adopted.

# 2. Apologies for absence

Apologies for absence were noted.

# 3. Declarations of interest

Dr Knudsen declared an indirect interest in the food additive DATEM (Item 12) and Dr Barlow an indirect interest in boron in natural mineral waters (Item 4).

# 4. Matters arising from the minutes of the 106th meeting (III/5157/97) and adoption of text of opinions adopted earlier

There were no comments on the minutes of the previous meeting. A proposal to replace the term "content level" by "nutrient density" in the opinion on maximum limits for vitamins and minerals in processed cereal-based foods and baby-foods adopted at the 105th Meeting (December 1996) was accepted.

## 4.1 Opinion on Natural Mineral Waters (final text with references)

The Secretariat explained that the opinion had been adopted at the 105th meeting (December 1996) but the references had only recently been completed.

Members drew attention to the fact that, although it had been made clear in the minutes of the 106th meeting that the Committee s approach to the estimation of the daily consumption of natural mineral waters was conservative but offered a certain flexibility for risk management purposes, this had not been made clear in the opinion itself. It was agreed to add a final section to the opinion to stress this point.

The full text of the opinion is annexed (Annex I)

## 4.2 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 (final text)

The Rapporteur recalled that following the 106th meeting, extensive editorial work related to the specialised terminology used in legislation on foods for infants and young children had been necessary and it had only been possible to issue a summary of the opinion which concerned 23 individual additives. These amendments had now been made, however the Rapporteur drew the attention of the Committee to two problems.

L-ascorbyl palmitate (E304): the Committee had agreed to industry s (IDACE) request for a use level of 10 mg/l in infant formulae and 15 mg/l in follow-on formulae both for infants and young children in good health and in FSMPs for the same age group. Subsequently, it had been realised that this was inconsistent with its earlier opinion expressed on the 27April 1983 (14th SCF Report Series) when the Committee had recommended a maximum level of 1 mg/100 ml (10 mg/l) for L-ascorbyl palmitate as a technological additive in infant formulae and follow-up milks. Further, since the upper limits for the fat content of infant formulae and follow-on feed are the same, there seemed to be no justification for a higher value in the latter product. IDACE had now confirmed to the Secretariat that a level of 10 mg/l in follow-on formulae was acceptable.

The Committee amended its opinion accordingly.

Diacetyltartaric acid esters of mono-and diglycerides (DATEM E 472e): the Committee had accepted the IDACE request for usage of DATEM in FSMPs for infants and young children at a level of up to 3 g/l in reconstituted products and 4 g/l in reconstituted products which are devoid of whole protein. A request for the same application for infants and young children in good health was not accepted. In the meantime a separate toxicological review of DATEM (Item 12) had been undertaken by the Additives Working Group during which it had been discovered that there was a substantial differences in the data provided by industry in two separate submissions for the levels of DATEM requested for the products concerned. Although the levels requested in most of the dry products (160 - 200 mg/100g) may lead to intakes at or just below the ADI (50 mg/kg b.w.) which the Committee found acceptable given the benefit derived from FSMPs for children in poor health, one product had a much higher level (1.6 g/100g) which could lead to intakes exceeding the ADI by up to a factor of up to 10.

Following the discussion on DATEM (Item 12), the Committee set a temporary ADI for DATEM of 25 mg/kg b.w. This, together with the above exposure considerations, led it to revise its advice concerning the use of DATEM in FSMPs for infants and young children.

The Committee concluded that DATEM is temporarily acceptable for a period of 2 years at levels up to 0.4 g/l, as consumed, in FSMPs which are devoid of protein and up to 5g/kg in gluten-free bakery products for coeliac patients.

The full version of the revised text is attached (Annex II).

### 4.3 Opinion on the additional information from the Austrian Authorities concerning the marketing of Ciba Geigy Maize

The full text of the opinion which was adopted at the 106th meeting is attached (Annex III).

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

**Commission actions resulting from SCF opinions**

The Secretariat reported that the Committee s opinion on maximum levels of vitamins and minerals in processed cereal based foods and baby foods (adopted at the 105th Meeting) had been incorporated into a draft Commission Directive on this subject.

# 6. Re-organisation of the Scientific Committees and renewal of mandates

The Chairman welcomed M B. Carsin, acting Director of the newly created Directorate B in DG XXIV with responsibilities for the Commission s Scientific Committees. M Carsin recalled the commitment given by M Santer to the EP in February to separate the management of the scientific advisory committees and control, inspection and audit activities from the Commission services responsible for legislation and policy. M Santer had also undertaken to report back to the EP in November 1997. M Carsin explained in detail the plans already announced in the Commission s

Communication on Consumer Health and Food Policy of 30 April 1997 for the setting up of a scientific steering committee to assist the Commission with the co-ordination of its specific committees and to deal with problems that were not covered by their mandates. The Commission Decision establishing the Scientific Steering Committee had been adopted on the 10th June 97. It would be composed of eight high level scientists from the field of consumer health together with the chairmen of the 6 specific committees. The Commission had at the same time approved the call for expressions of interest from persons wishing to serve on the Committee together with the eligibility and selection criteria copies of which were distributed to Members. Anyone who satisfied the eligibility requirements could apply and the selection procedure would take place under the Chairmanship of an eminent and independent scientist. M Carsin outlined the planning for the renewal of the mandates of the 6 specific committees and re-nomination of Members. A call for expressions of interest from persons wishing to be considered for membership of the individual Committees would also be published and would be followed by a selection procedure in which the Commission would be assisted by the eight experts of the Steering Committee who would already have been nominated. The calls for expressions of interest will be formally published in the OJ but steps were being taken to ensure their widest diffusion. It was hoped that the new Committees would be fully operational by the end of October 1997 which would require the call and selection procedure to be completed by late September. Committee Members were encouraged to distribute copies of the calls as widely as possible.

Members took the opportunity to discuss with M Carsin specific points concerning the operation of the reconstituted committees and to express individual concerns relating to the proposed changes.

The Chairman thanked M Carsin on behalf of the Committee for his detailed and frank summary of the situation.

# 7. Endocrine disruptors

The Rapporteur presented her report on the meeting with the Association of Plastic Manufacturers of Europe (APME) which had been arranged to assess how the APME might assist the SCF with its risk assessment work related to "endocrine modulators" primarily in the area of materials in contact with food. The Rapporteur had presented a paper on the SCF s position (opinion expressed in June 1996) on endocrine disruptors in food, its recent work on phthalates and BADGE and its proposed work programme. Papers were presented by industry summarising on-going work and interim results on bis-phenol A, phthalates and on nonyl phenol and nonyl phenyl ethoxylates. The Rapporteur s report identified substances that will need to be examined in the context of food contact materials when the results of current studies are available e.g. 4-t-octyl phenol, nonyl phenol and bisphenol A. The Rapporteur identified a need for the Committee to initiate a review of naturally occurring oestrogens in foods and to develop guidelines for the evaluation of endocrine disruptors.

Members welcomed and endorsed the report. The Committee agreed with the Rapporteur s assessment that it would be prudent to wait until the current high level of research activity had clarified some fundamental questions relating to, for example, the interpretation of *in vitro* and some common *in vivo* tests with respect to the implications for human health.

It was concluded that this was an area where the SCF should remain vigilant and although it may be too early to initiate detailed risk evaluations on endocrine disruptors in general, it would be helpful to continue to assign one Member to follow developments. An early task for the reconstituted Committee should be the stimulation of appropriate actions in the framework of DG XII Research Programmes.

# 8. Requests for opinions

The Secretariat reported that the requests for evaluation of the following food additives had been received; ethyl hydroxyethyl cellulose, TBHQ, stevioside, riboflavin by fermentation and cross linked carboxymethyl cellulose (crosscarmellose). They had already been passed to the Additives Working Group for action.

It was agreed that the Secretariat would arrange for the relevant dossiers to be examined by the Working Groups on Food Hygiene and Microbiology and on Novel Foods and Processes where appropriate.

# 9. Novel Foods

The Chairman of the Working Group reported that its preparatory work is complete. It is now awaiting comment resulting from the publication of the Commission Communication on scientific aspects of submissions and preparation of initial assessment reports which are based on the SCF s guidelines

# 10. Nutrition and Dietetic Foods

**Beta-carotene - high dose studies**

The Chairman of the Additives Working Group summarised the conclusions of the discussion on this subject which had taken place at the Additives Working Group meeting of the previous day which had also been attended by a Member of the Nutrition Working Group. The Committee debated the question at length and concluded as follows.

The Committee has reviewed in detail the published studies on the use of -carotene supplements in preventive and therapeutic trials. In preventive studies doses up to 50 mg/d and in the therapeutic trials up to 180 mg/d were given.

Contrary to expectations some of the preventive trials showed no protective effect in the general population and an increase of cancer incidence in smokers taking -carotene supplements.

This raises the question of whether -carotene exacerbates the effects of known carcinogens. While it would be premature to draw any final conclusions the Committee did however feel that it should review the scientific basis of the current ADI of 5 mg -carotene/kg b. w. and sources of exposure in the diet.

After an examination of the existing human and animal data the Committee concluded that at present there is an insufficient basis for establishing an upper safe limit in humans which could be confidently said to be without any adverse effect. Equally it is not possible to establish a new ADI at this point in time. However, the Committee considers that the present ADI, which would theoretically allow intakes up to 350 mg/d (for a 70 kg adult) is too high.

Available intake data from several European countries indicate that natural food sources of -carotene may contribute around 2-5 mg/person/day and food additives around 1-2 mg/person/day for the average consumer. Possible total exposure from these two sources may therefore be of the order of 10 mg/day. Intake of this magnitude is regarded as safe, moreover it may confer health benefits.

An additional source of exposure is from supplements. Given the findings from human trials, the Committee has however some concerns that the use of -carotene as (dietary) supplements may lead to a total intake in excess of 20 mg/day. Further studies are required to resolve these concerns.

The Committee will continue to address the issue of establishing an upper safe limit for -carotene intake in humans.

It was agreed the Rapporteur for the review on the effects of ß-carotene supplementation in combination with tocopherol and ascorbate in clinical and chemopreventive trials, which had been disussed at the 106th Meeting, would complete the work by addition of draft conclusions in collaboration with other Members of the Nutrition Working Group, for submission to the September 97 Plenary meeting.

# 11. Applicability of the ADI to infants

The Rapporteur recalled that the Committee had discussed this matter at the 105th and 106th meetings and it had also been the subject of an ILSI meeting in February 97 in which Members of the Committee had participated. He introduced the draft opinion which had been modified as agreed at the 106th meeting. Members debated the extent to which it was justified to consider the ADI concept to apply to the entire population (including infants, the young, old, immuno-suppressed and the pregnant), or whether certain sub-sections of the population may be exceptions to the overall concept **.**

It was agreed that the present question should focus on the exposure of infants to food additives and that the paper should be redrafted with this in mind for finalisation at the next meeting. It was further agreed that the Committee would develop a separate opinion in relation to pesticides and food contaminants.

# 12. Food Additives

## 12.1 Isomalt (notification of new production method under 95/31/EC)

The Secretariat recalled that at its 103rd meeting (September 96), the Committee had agreed the procedure to be followed when it was requested to evaluate the safety implications of significant changes to the production method or starting materials under the provisions of Commission Directives on specific purity criteria for additives for use in foodstuffs. It had decided that detailed toxicological evaluation would only be undertaken if the information provided gave rise to concern over the presence of new hazards. It was also agreed that the initial evaluation should be the subject of an oral report by the Rapporteur to the Additives Working Group and that the Plenary would be informed of the outcome which would be recorded in the minutes of its meetings. Isomalt was the first example of the application of this procedure.

The Rapporteur reported that the petition concerned the preparation of isomalt (E 953) by an alternative refining process based on enzymatic hydrolysis. This resulted in a product that differed from that refined by crystallisation mainly in that the sorbitol and mannitol contents were higher (4.5 and 2.5 % respectively) and in the distribution of minor components (mainly saccharides and saccharide alcohols). The Working Group had recently received clarification of the nature of previously unspecified minor components and were satisfied that the material was sufficiently well defined to allow a specification to be established if necessary.

The Committee concluded that, on the basis of the information supplied, it had no reason to consider that the proposed change in the method of production of isomalt would give rise to concerns for public health.

## 12.2 Adoption of an opinion on Diacetyltartaric acid esters of mono-and diglycerides -DATEM, E 472e. (See also the discussion of DATEM under Item 4)

The Chairman of the Working Group stressed that the current interest in DATEM arose from the inadequacy of the toxicological data-base and not because of any inherent concern for the safety of the substance.

The Rapporteur presented the draft opinion which was accepted with only minor editorial amendments. The opinion concludes as follows:

The Committee is unable to express a view on whether E 472e is acceptable for use in formulae and in follow-on formulae based on hydrolysed proteins for infants in good health and in the meantime considers that it should not be used in such products. As mentioned previously, the Committee has already agreed to the temporary use of E 472e for two years in FSMPs.

The Committee will reconsider the request for use in formulae and in follow-on formulae based on hydrolysed proteins for infants in good health, its recent temporary acceptance for use in FSMPs and the temporary ADI now set for general food use once the following information is supplied, or within two years of the date of this opinion, whichever is the earlier:

1. i. An adequate specification which should include a limit for tartaric acid of 20 % of the preparation
2. ii. Full submission of the recently completed long-term study in laboratory animals
3. iii. Studies on reproduction and teratology conducted to modern standards
4. iv. A test for chromosomal aberrations in mammalian cells *in vitro*

The full text of the opinion is given in Annex IV.

## 12.3 Adoption of an opinion on lecithin

The Rapporteur recalled that at its 106th meeting (March 97), the Committee had requested the Additives Working Group to give further consideration to the question in the light of additional information on the composition of commercial lecithins which should be provided by industry.

He reported that he and another Member had met representatives of the lecithin producers and users under the auspices of IDACE at the end of April 97 and it had been agreed that additional specified information would be provided in time for discussion at the Additives Working Group meeting on 10 June 97. Unfortunately, the information which had only very recently provided was incomplete and it was not therefore possible to conclude on this matter before the September 1997 Plenary.

## 12.4 Adoption of an opinion on wood rosins

Deferred to the September Plenary due to lack of time.

## 12.5 Aspartame (minute statement)

The Rapporteur recalled that at its 105th meeting (December 1996) the Secretariat had drawn the attention of the Committee to recent press reports concerning an alleged connection between aspartame and increase in the incidence of brain tumours in the USA. The Committee noted that the US FDA had recently issued a statement in which it endorsed it opinion that there were no grounds for concern and that the UK s Committee on Carcinogenicity (COC) was re-examining data on this issue. At that time, the Committee proposed to review the situation on receipt of the COC report which had now been made available to it. The Committee adopted the following statement:

At the 105th Plenary meeting the Committee's attention was drawn to press reports alleging a connection between aspartame and increases in the incidence of brain tumours in the USA. These reports followed publication of a paper by Olney and co-workers (Journal of Neuropathology & Experimental Neurology 55, no 11, 1115-1123, November 1996) which concluded that there was a need to reassess the carcinogenic potential of aspartame.

The Committee was aware that the US Food and Drug Administration (FDA) had already considered the matter and had stated that analysis of the National Cancer Institute public database on cancer incidence in the United States does not support an association between the use of aspartame and increased incidence of brain tumours. The FDA stood behind its original decision to approve the use of aspartame as an artificial sweetener (FDA Statement on Aspartame. Talk Paper T96-74, November 18, 1996).

The Committee has since been informed about a detailed analysis of the data presented by Olney and co-workers undertaken by the UK Department of Health's Committee on Carcinogenicity (COC). The COC concluded that the data did not raise any concerns with regard to aspartame use.

The Committee has also itself examined the report of Olney and co-workers and agrees with the views expressed by other bodies concerning the validity of the analysis and conclusions drawn by Olney *et al.*. The Committee has concluded that the data do not support the proposed biphasic increase in the incidence of brain tumours in the USA during the 1980s.

The SCF therefore advises the Commission that there is no new evidence to justify a re-examination of aspartame by the Committe **e.**

## 12.6 Draft opinion on microcrystalline cellulose (MCC)

The Rapporteur introduced the draft opinion which had been amended following the discussion at the 106th Meeting (March 97). He stressed that recent work, which showed the importance of preventing air-borne particulate contamination of the samples, cast doubt on the extent of persorption that had been reported in earlier studies. In one

such study, some particles were reportedly found in the tissues and some impairment of renal function was noted, but neither histopathological kidney lessions nor any microemboli were observed. A summary only of this report was available to the Committee. After 2-years exposure, there were no detectable particles in tissues or treatment-related adverse effects on kidney structure and function or on other organs. Members discussed whether there might be adverse effects from persorbed particles which were not detected in the older animals showing age-related changes in this study. Members also noted that additional documentation had apparently been submitted for the forthcoming JECFA evaluation. Members recommended that it should be made clear that reference to the 10 % tolerance on a particle size of 5 µm referred to the distribution of the number of particles (in accordance with the use of a low angle laser scattering method for the determination of the particle size distribution).

In these circumstances, the Committee recommended that the draft opinion be revised to take account of the discussion and the outcome of the JECFA review, particularly with respect to the findings in the additional studies seen by JECFA, with a view to re-submission at the September 97 Plenary.

The Secretariat confirmed that, currently, MCC is not approved in the EU for use in foods for infants and young children and that the current petition did not seek extension of conditions of use.

## 12.7 Adoption of an opinion on canthaxanthin

In introducing the draft opinion, the Rapporteur stressed that under current Community legislation, food additive use of canthaxanthin is restricted to its use as a colouring material for Saucisse de Strassbourg and that, in practice, its use as a feed additive for poultry and fish production resulted in greater dietary exposure. He recalled that the Committee had established a t-ADI of 0 - 0.05 mg/kg b.w. at its 74th Meeting (June 1990). The Working Group had now completed a review of additional data submitted since the previous opinion and recommended the Committee to set a full ADI of 0-0.03 mg/kg b.w.

The Committee accepted this recommendation, however, in view of the low ADI and the lack of exposure data to allow an assessment of the likelihood of the ADI being exceeded, Members requested that the opinion be amended to emphasise the need for an assessment of dietary exposure from all dietary sources of canthaxanthin (i.e. food and feed additive use). The conclusions of the opinion are as follows:

The lowest effect level for ERG b wave changes in man was 0.25 mg/kg b.w./day but in view of the fact that these changes were not of pathological significance or indicative of significant functional damage to the retina, a safety factor of 10 is considered appropriate.. This is supported by the finding of a one order of magnitude difference between the plasma level (156 µg/L) at the NEL in monkeys and the in vitro concentration (1200 µg/L medium) first showing the presence of cellular microcrystal formation in neuronal retina reaggregate cultures. An ADI of 0.025 mg/kg b.w., rounded up to 0.03 mg/kg b.w., can therefore be established.

The Committee considers that up to date information should be obtained on human intake from the use on canthaxanthin in animal feeds to give assurance that total exposure by this route would not exceed the ADI.

The full opinion is given in Annex V.

## 12.8 Adoption of an opinion on algal -carotene

The Rapporteur introduced the draft opinion and explained that it resulted from a long series of communications with the petitioner in order to clarify aspects of the production process and quality control procedures which were relevant to the risk assessment. Members requested that the draft opinion be amended to clarify the relationship between *Dunaliella salina* used in the bio-reactor and *Dunaliella bardawil* which had been used to produce the material used in the short term study and to give more explicit information on the nature of the major and minor impurities.

The Committee concluded as follows:

On the basis of the information provided, the Committee considers that the use of a dispersion of beta-carotene

produced by the alga *Dunaliella salina* growing in large, shallow saline lakes in Whyalla, South Australia, is acceptable as a food additive. This opinion is expressed on the basis of a maximum use level of this preparation of around 50 ppm (equivalent to around 10 ppm of beta-carotene).

This conclusion is valid only for the beta-carotene produced in the conditions and at the sites described in the dossier provided by the petitioner which provided reassurance on the composition and relative purity of the material. A specification should be developed which complies with all the above information and recommendations.

The complete text is given in Annex VI.

# 13. Materials and Articles in Contact with Food

## 13.1 Adoption of a report "Additional list of monomers and additives"

The Working Group Chairman presented the report which concerned 5 monomers and 5 additives. It was agreed to amend the report to specify the scope of lists 4a and 4b.

The report was adopted (Annex VII)

## 13.2 Clarification and explanation of the SCF opinion on BADGE (expressed on 7 June 1996)

The Chairman of the Working Group explained that, following its opinion on BADGE expressed at its 102nd Meeting (7th June 1996), the Committee had been requested by the Commission to provide a more detailed explanation for its decision to change the classification of the substance from list 4 to list 7 with special emphasis on the mutagenicity data. Further, it was asked to specify the hydrolysis products which are included in the upper limit of 1 mg/kg of food as a temporary restriction for specific migration of BADGE and its hydrolysis products.

The Committee accepted the clarifications which are set out in full in Annex VIII.

# 14. Flavours

No discussion

# 15. Contaminants

## 15.1 Adoption of an opinion on Nitromusk compounds

The Committee concluded as follows:

Musk xylene is carcinogenic in mice and, given that a number of tests did not reveal a genotoxic potential, it is probably acting through a non-genotoxic mechanism in mice. On the other hand it must be taken into account that musk xylene is metabolised in rats and humans to aromatic amines. In addition, musk xylene is an enzyme inducer and accumulates in body tissues because of its lipophilic nature. It is found in human milk and adipose tissue. The half-life in humans is long in contrast to rats and mice. For these reasons, in the opinion of the Committee, contamination of food with musk xylene should be reduced as much as possible.

The toxicological data on musk ambrette, musk ketone, musk tibetene and musk moskene are insufficient to allow a reliable evaluation or to provide a basis for the setting of tolerable levels in food. These nitro musk compounds must also be expected to have a high tendency to accumulate. It is therefore the opinion of the Committee that, as a matter of prudence, contamination of food with these compounds should also be reduced as much as possible.

The full opinion is given in Annex IX.

## 15.2 Adoption of an opinion on the transport of raw sugar in non-dedicated vessels

Deferred to the September 1997 Plenary due to lack of time.

## 15.3 Methyl esters of fatty acids in previous cargoes (amendment of previous opinion)

The Committee agreed the following amendment to its opinion of 20 September 1996 (102nd Meeting) on acceptable previous cargoes:

The item "Fatty Acid - Methylesters (laurate, palmitate, stearate, oleate) can be transferred to Annex I as acceptable previous cargo. The reason for this change in the Committee's advice is the recent supply of additional information enabling a re-evaluation of these substances. The methyl esters of fatty acids all occur in trace amounts in natural oils and fats. Their chemical constitution make it unlikely that their ingestion would cause any health problems, if present in edible oils and fats in trace amounts. The information now supplied on cleaning and processing confirms, that these esters would be easily removed by tank cleaning and that processing of the edible fats and oils would reduce their presence to insignificant levels in the refined food products.

## 15.4 Adoption of a statement on 3-monochloropropan-1,2-diol (3-MCPD)

The Chairman of the Working Group recalled that at its 105th meeting on (December 1996) the Commission had requested the Committee to re-examine the conclusion of its opinion expressed on the 16 December 1994 that 3-MCPD must be regarded as a genotoxic carcinogen in the light of an industry commissioned report which challenged this conclusion.

The Committee endorsed the following conclusions of the Contaminants Working Group:

The Contaminants Working Group has reviewed the safety evaluation of 3-monochloro-propandiol (3-MCPD) prepared by CANTOX INC for the International Hydrolysed Protein Council. This document does not present any new evidence. The conclusions drawn by CANTOX are based on a different interpretation of the same studies, which had been reviewed by the SCF before its opinion was expressed in 1994. All data quoted by CANTOX including negative results of *in vivo* genotoxicity tests, data on metabolic pathways and indications for hormonal mediated carcinogenesis had been considered during the preparation of the SCF opinion.

Therefore, it was concluded that there is no reason for the Committee to change its opinion on 3-MCPD as expressed on 18 December 1994.

As a matter of general principle, the Committee stated that in those cases where the Committee is requested to reconsider its opinions in the absence of new scientific information, it will not be inclined to undertake a complete re-evaluation of the question.

# 16. Food Microbiology and Hygiene

## 16.1 Adoption of an opinion on principles of risk assessment of micro-biological hazards

The Chairman welcomed the document noting the importance of the document which set out the vocabulary and concepts to be applied in this difficult area. The Rapporteur commented that the report had resulted from excellent collaboration between the Working Group and Scientific Co-operation Task 2.1 on micro-biological risk assessment. Members paid particular tribute to contribution and guidance of Prof. Jouve in both groups and considered that the report would be invaluable in the context of CODEX discussions related to HACCP.

The opinion was adopted without amendment (Annex X)

### 16.2 Adoption of an opinion on the potential micro-biological risk arising from the presence of moisture in tea

Deferred to the September 1997 Plenary due to lack of time.

### 16.3 Discussion paper on microbial resistance in food organisms

Deferred to the September 1997 Plenary due to lack of time.

## 17. Intake and Exposure

No discussion

## 18. Scientific Co-operation

No discussion

## 19. Any other business

The Chairman asked members to let him have any comments on the proposals for the re-organisation of the Scientific Committees during the Summer period. He undertook to collate them and pass them to DG XXIV on behalf of the Committee.

## 20. Adoption of minutes

The minutes were adopted by a written procedure.