Minutes of the 108th Meeting of the Scientific Committee for Food held on 18 - 19 September 1997 in Brussels

ATTENDANCE LIST - LISTE DES PARTICIPANTS - TEILNEHMERLISTE

Members/Membres/Mitglieder

- MME. S. BARLOW
- MM. D. BOSKOU, J. A. AMORIM CRUZ, P.J. AGGETT, A. CARERE, I. ELMADFA, M. GIBNEY
- MME. A. FERRO-LUZZI (Vice-Chairman, Vice-President, Stellv. Vorsitzender)
- MME. A. KNAAP
- MM. I. KNUDSEN (Vice-Chairman, Vice-President, Stellv. Vorsitzender), J. T. KUMPULAINEN, S.E. LINDGREN, G. PASCAL (Chairman, President, Vorsitzender), A. SOMOGYI, R. WENNIG

Apologies/Excusés/Entschuldigt

- MM. A. HUYGHEBAERT, W. HAMMES, C. NOMBELA CANO
- MME. O. TELLO ANCHUELA

EFTA/EEA Observer

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

Others/Autres/Andere

-

Commission/Kommission

- MME. C. MAJEWSKI (DG III/E/1)
- MM. M. GRANERO ROSELL (DG III/E/1), B. MATHIOUDAKIS (DG III/E/1) (point 11)
- Mme M.P. DARCHY (DG III/E/2)
- M. F. VERSTRAETE (DG VI/B/21)
- M. B. LEFEVRE (DG VI/E/2) (point 7)
- M. S. BOHR (DG XV/B/2)

Secretariat/Serétariat/Sekretariat

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

1. Adoption of the agenda

The agenda was adopted. The Chairman's proposal to have an initial discussion on urgent questions relating to

pesticides in baby food and aflatoxins on the first day was accepted.

2. Apologies for absence

Apologies were noted. The Chairman reported that Professor Rey had resigned membership of the Committee in July in order to take up an advisory position in the French administration. The Committee expressed its appreciation for the outstanding contribution that Prof. Rey had made to the Committee during many years as an SCF Member.

3. Declarations of interest

No declarations were made in relation to matters on the agenda.

4. Matters arising from the minutes of the 107th meeting

DATEM (E 472e): Members recalled that in its opinion on DATEM of 13 June 97, it had expressed the wish to see the full presentation of the recently completed long-term feeding study in laboratory animals within 3 months. The Secretariat reported that it had already received a letter from the EFEMA (European Food Emulsifiers' Association) in response to the Committee's Minute statement in which it had undertaken to co-operate fully with the Committee.

The Secretariat reported that, in line with the new policy of transparency relating to the Commission's scientific committees, the 11 opinions adopted by the Committee at the 107 th meeting together with the minutes had been made available on the internet via the Commission's Europa Server (DG 24 Home page) within 3 weeks of the meeting.

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 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 adopted at its 106 th meeting had been fundamental to the amendment to the EP and Council directive on miscellaneous additives which were currently under discussion.

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

The Secretariat reported that the Commission had adopted a Decision establishing the 8 specific scientific committees on 23rd July 1997. Arrangements had been made to complete the evaluation of applicants for membership of the Committees in the following two weeks and it was hoped that the Committees would be operational by mid-November. In response to questions, the Secretariat said all efforts were being made to minimise disruption to the work of the Committee and that as far as possible, working groups would continue in the intermediate period.

7. Requests for opinions

The Committee formally received requests for opinions on the following questions:

7.1 Urgent questions where the Committee had been requested to deliver an opinion at this Meeting

Scientific basis for the labelling of genetically modified maize and soya (See item 8)
- Pesticides in foods for infants and young children (See item 11)
- Aflatoxins (See item 15)

7.2 Other questions

Patulin and ochratoxin A

The Committee had last considered the human toxicology of these mycotoxins in its opinion on aflatoxins, ochratoxin A and patulin expressed on 23 September 1994 (35 th Report Series). Since that time, a number of new studies had been completed. The Commission services are currently examining the possibility of introducing limits for patulin and ochratoxin A in certain products and it had become urgent to have the opinions re-examined in the light of the new data. This was particularly important for ochratoxin A for which recent studies had reopened the debate on its genotoxic potential, a matter of fundamental importance for the setting of any limits.

Several Members expressed interest in participating in discussions of this issue and suggested names of experts. The question was assigned to the Contaminants working group

Lycopene

Assigned to the Additives working group

Urease treatment of wine

Assigned to the Additives working group and to be evaluated in accordance with the Committee's guidelines for the evaluation of enzymes

8. Novel foods

Scientific basis for the labelling of genetically modified maize and soya

The Chairman commented that questions of labelling were not related to risk assessment and did not therefore fall within the mandate of the SCF. There was a serious risk that discussion of a labelling question by the Committee might be misinterpreted as implying that there was a concern for public health.

The Rapporteur presented the draft opinion which related to an urgent request from the Commission concerning the labelling of genetically modified maize and soya. The draft opinion had been prepared following detailed discussion at the Novel Foods Working group meeting on 4 th September 97. The Working Group had been at pains to stress the distinction between the term equivalence used in Commission Regulation (EC) No 258/97 where it refers to the inherent compositional characteristics of a food or food ingredient and the concept of substantial equivalence used by the Committee and bodies as a basis for risk assessment of novel foods and processes.

Members proposed a series of amendments to stress amongst other things that the opinion did not imply concerns for public health and that the Committee had considered it more appropriate to address the question in general terms rather than to examine the specific issues of genetically modified maize and soya.

The Committee concluded as follows:

This opinion delineates the presently known technical possibilities for monitoring and control as well as the associated limitations for labelling purposes.

The SCF emphasises that "equivalence" is a legal term which applies to the inherent analytical compositional characteristics of a food or food ingredient, whereas "substantial equivalence" represents a safety and nutritional evaluation of such products in comparison to appropriate predecessors.

The SCF advises that safety and nutritional data used for the evaluation of substantial equivalence may also contribute to the basis for the identification of measures to monitor the correct implementation of labelling and the spread of novel foods in the market place. The application of the data for this purpose will have to be established on a case-by-case basis paying particular attention to key macro- and micro-nutrients and to potential toxic and anti-nutritional factors which might be either inherently present or process derived.

The Committee suggests based on its considerations, that if obligatory labelling requirements for novel foods which from a legal point of view are no longer equivalent to traditional foods are introduced, they should for practical reasons be combined with a management decision to introduce an acceptable level for the accidental mixing of the safe novel food with its conventional counterpart.

Furthermore, analytical methods should be employed that are standardised and validated. For determination of recombinant DNA in a food or food ingredient, all available information concerning unique sequences should be revealed for use by control laboratories

The Committee also points out that foods which have been shown to be substantially equivalent and to be as safe as their traditional counterparts, may contain modified DNA but otherwise be identical to their traditional counterpart. In such cases, this DNA, although it does not change the composition and safety of the final food product, may facilitate monitoring and control.

The full text of the opinion is given in Annex I

9. Nutrition and Dietetic Foods

Beta-carotene - high dose studies

Members recalled that the question had been discussed at the 107 th Meeting where it had been agreed that the Additives Working Group would consider the possibilities for revision of the ADI for Beta-carotene. The Rapporteur for the general question of the implications of the high dose studies for dietary exposure undertook to complete the report for discussion at the December Plenary meeting.

10. Applicability of the ADI to infants

The subject was deferred to the next meeting due to lack of time

11. Pesticides in foods for infants and young children

Prof. Pascal introduced the draft opinion and explained that it had been prepared at an *ad hoc* meeting on 28/29 August 97 which had been organised in response to a request from the Commission for an urgent opinion relating to a draft proposal from the Commission services for a common MRL of 0.01 mg/kg for pesticides in manufactured foods intended for infants and young children. A number of *ad hoc* experts had been invited to attend including the Chairman and a vice-Chairman of the Scientific Committee on Pesticides, Prof. Jouany and Prof. Fernandes respectively. Particular thanks were given to Dr J Chr. Larsen of the Danish Veterinary and Food Agency who had kindly agreed to be Rapporteur and had prepared an excellent draft opinion following the first day's discussion. The working group had begun by examining the fundamental questions of the applicability of the ADI to infants and young children and whether in general terms the existing toxicological data-bases on which the ADIs are based were adequate to protect this group of the population. The working group had paid considerable attention to the estimation of the amount of commercial manufactured infant formulae (dry), cereals and milk cereals (dry), and other ready-to-eat weaning foods and baby foods consumed by infants and young children.

Members recommended that estimation of food consumption by this age group should be validated by comparison with

estimates based on energy requirements and that the opinion should make it clear that the limit of 0.01 mg/kg has not been proposed on the basis of toxicological evaluation.

The Committee concluded as follows:

The Committee is asked to advise the Commission as to whether a maximum residue limit (MRL) of 0.01 mg/kg for pesticides in manufactured foods intended for infants and young children (dietetic foods) would be adequate to protect the health of this section of the population or whether there are instances where there are reasons to be concerned that the presence of even lower levels might constitute a risk. It concludes as follows:

The ADI covers all groups of the population. The Committee does not recommend the use of special uncertainty factors for infants and children or the establishment of special ADIs for this age group. The toxicological database should adequately cover the most sensitive effects and the most sensitive age groups and the ADI should cover all sensitive segments of the population, irrespective of age. If there is scientific evidence that infants and children are the most sensitive populations to a particular pesticide, that evidence must drive the derivation of the ADI.

The Committee recognised that the currently used data package for the establishment of the ADI was not in all respects optimal to reflect a particular sensitivity of infants towards the potential toxicity of a given pesticide. However, it was the opinion that in most cases the toxicological studies would have provided indications if such special sensitivities were to exist. The Committee concluded that the current ADIs would provide a reasonable basis for evaluating the health impact of pesticides in foods intended for infants and young children.

The fact that infants and children have a relatively higher intake of some food items than adults should clearly be considered in the risk assessment. This is not always taken into consideration when setting MRLs.

The Committee considered 0.0005 mg/kg b.w to be a realistic worst case estimate for the upper limit for the daily intake of a pesticide arising from the consumption of manufactured infant formulae (dry), cereals and milk cereals (dry), and other ready-to-eat weaning foods . The estimate assumes that all infants and young children consume commercial products at the highest recorded 95 th percentile every day and that all commercial products contain the pesticide at a level of 0.01 mg/kg in the products as sold.

The Committee concluded that if the maximum residue limit were to be set at 0.01 mg/kg in foods intended for infants and young children, there is a possibility that an infant could exceed the ADI for pesticides having an ADI at 0.0005 mg/kg b.w. or lower

This would imply that the Commission and the Member States should carefully reconsider pesticides that have been allocated ADIs at 0.0005 mg/kg b.w. or lower as to the health impact of their presence in baby food. This consideration should include an examination of their actual use and the basis on which the ADIs was set, i.e. whether the toxicological data package gives any reason for special concerns for infants and children.

The Committee was also aware that some pesticides share a common mechanism for their critical toxic effect which determined the ADI, but do not necessarily share a group ADI. The Committee recommends that further consideration be given by the appropriate bodies to the potential for additive effects and whether the risk management of residues in foods specially manufactured for infants and young children needs to take these into account.

In giving its opinion, the Committee wishes to note that the limit of 0.01 mg/kg has not been proposed on the basis of toxicological evaluation. Therefore, for those pesticides having an ADI greater than 0.0005 mg/kg b.w., their presence in foods intended for infants and young children at levels exceeding 0.01 mg/kg does not necessarily imply a risk to their health.

When setting MRLs for pesticides in foods intended for infants and young children, the Committee draws attention to limitations of current routine analytical methods for determination of some pesticides particularly at levels around 0.01 mg/kg.

The Committee notes that pesticides are subject to continuous re-evaluation within the EC and elsewhere, and

recommends that special attention is paid to the potential higher susceptibility of infants and children to certain compounds during this process. This will require further research which may lead to improved test strategies.

The full text of the opinion is given in Annex II

12. Food Additives

12.1. Adoption of an opinion on wood rosins

The draft opinion was adopted with minor editorial amendment. The Committee concluded as follows:

The question of whether the coating materials requested for inclusion in Annex IV of the Directive on Food Additives other than Colours and Sweeteners are in fact produced from appropriately modified wood rosin cannot be verified by the Committee until the revised specifications become available. Meanwhile, the Committee is of the opinion, that coatings made from partially hydrogenated wood rosin are ***temporarily acceptable*** *as coatings for fresh citrus fruits at an application rate of 50 mg/kg fruit. This decision is based on the available though limited feeding studies in rats and dogs, which indicate a safety margin of 75-500 between likely intakes and the NOAEL. The Committee requires information on reproductive effects, teratogenicity, mutagenicity and an adequate specification defining the source of the rosin within the next three years.*

For coatings made from the pentaerythritol ester of wood rosins the Committee considers that these are ***temporarily acceptable*** *for use on fresh citrus fruits at an application rate of 50 mg/kg fruit. This decision is based on the available though inadequate long term studies in the rat and dog and the reasonably adequate 90-day rat study none of which disclose any significant adverse toxicological effects. The acute toxicity is also very low and hydrolysis is unlikely in view of the stable chemical structure of the ester. The safety margin between likely intakes and the NOAEL lies between 10 and 60. However appropriate information on reproductive effects, teratogenicity and mutagenicity is required within the next 3 years and an adequate 2 year oral feeding study in rats is required within 5 years. An adequate specification defining the source of the rosin is also required.*

The Committee is unable to evaluate the safety of rosin modified by maleic anhydride and esterified with pentaerythritol because of the grossly inadequate toxicological database and the uncertainty regarding the specification of this modified wood rosin. The Committee therefore considers this modified resin ***unacceptable*** *for food use.*

The full text of the opinion is given in Annex III

12.2. Adoption of an opinion on microcrystalline cellulose (MC)

The Chairman of the Additives working group explained that it had been possible to give further consideration to the question of persorption which had been raised at the 107 th meeting in the light of the JECFA evaluation (49 th meeting in Rome, June 1997). The additional studies presented to JECFA and at a later stage to the SCF, were relevant and consideration of these, together with the rest of the available studies, provided satisfactory evidence concerning persorption issues and the absence of kidney effects in adults. The Committee consequently adopted the revised opinion with only minor amendments. The opinion concludes as follows:

This opinion applies only to general food uses of MC and does not apply to use in foods specially prepared for infants and young children including foods for special medical purposes for the same age group.

The additional toxicological information now submitted confirms the validity of the ADI "not specified" for MC previously established by the Committee. There is now evidence that MC has neither genotoxic nor teratogenic potential in the rat.

Early studies on the intestinal persorption of MC of varying particle size suggested that MC is persorbed, particularly if the particle size is <5 µm. This process is however very inefficient, at least in adult animals, and does not result in

microembolic phenomena, nor does it appear to interfere with the immune function of the GALT. Recent studies on persorption in several species have shown that the rat provides an adequate model for this process in man. The two-year feeding study in rats showed no evidence of any histopathological or functional effects ascribable to accumulation of MC particles in any tissue as a consequence of persorption. The available human data on particles other than MC and animal studies on MC and the GALT suggest, that in normal adults, exposed over a comparatively short period, the intestinal persorption of MC of particle size even down to at least 5 µm would be unlikely to cause any adverse pathology in the gut and GALT. The Committee wishes to stress that there are no data available on the existence and the extent of persorption in very young animals or in human infants.

As a precautionary measure however, the Committee reiterates its view of 1993 (3) that the specification of MC should include a restriction on the content of material of particle size <5µm, The Committee is aware that a tolerance of 10% by number of particles is achievable. Otherwise the Committee's views on MC remain unchanged.

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

13. Materials and Articles in Contact with Food

No matters were raised

14. Flavours

No matters were raised

15. Contaminants

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

The Secretariat explained that following previous discussions in the Committee, the draft opinion had been amended to recognise that cleaning prior to transport of raw sugar or of semi-processed syrups and thick sugar juices could be considering to be a critical control point within the terms of Article 3 of the Hygiene of Foodstuffs Directive which refers to the principles of HACCP systems. The opinion was adopted with minor amendments the conclusions being as follows:

The Committee notes that this request for a derogation relates to a well established industrial practice with a long history of safe use. It concludes that, on the basis of the information available to it, it has no reason to believe that the transport of raw sugar or of semi-processed syrups and thick sugar juices in non-dedicated vessels and in accordance with best industrial practices is likely to give rise to risks to public health.

The Committee was informed that, in practice, ships used for bulk transport of raw sugar are generally unsuitable for bulk transport of liquids.

It noted that the cleaning and control procedures applied during transport of raw solid and unrefined liquid sugars are not well defined in all cases. Furthermore, it appeared that judgement of the acceptability of the cargoes carried prior to bulk semi-processed syrups and thick sugar juices is to some extent discretionary.

In view of the above considerations, the Committee recommends that any derogation be subject to the following additional safeguards:

Transport of raw sugars

- *- effective cleaning procedures should be introduced to ensure that contamination from transport containers or previous cargoes does not result in a risk to health arising from the consumption of refined sugar. This may be*

achieved by considering cleaning to be a critical control point within the terms of Article 3 of the Hygiene of Foodstuffs Directive which refers to the principles of HACCP systems

- *- the prohibition of the use of liquid previous cargoes in bulk for the transport of raw sugar.*

Transport of unrefined liquid sugars (semi-processed syrups and thick sugar juices)

- *- effective cleaning procedures should be introduced to ensure that contamination from transport containers or previous cargoes does not result in a risk to health arising from the consumption of refined sugar. This may be achieved by considering cleaning to be a critical control point within the terms of Article 3 of the Hygiene of Foodstuffs Directive which refers to the principles of HACCP systems*
- *- a list of acceptable previous cargoes.*

The Committee's conclusions are applicable to the bulk transport of raw sugars and semi-processed syrups and thick sugar juices which will undergo a full and effective refining process before use as food or food ingredients

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

15.2 Request for urgent opinion on the JECFA report on aflatoxins prepared at its 49th meeting, Rome 1997)

The Commission had asked the Committee at short notice to give its advice concerning the JECFA report on aflatoxins adopted at its 49 th meeting in Rome, June 1997. The Rapporteur recalled the previous opinion of the SCF on aflatoxins, expressed on 23 rd September 1994, and introduced the recent JECFA (1997) evaluation on the basis of the summary and conclusions of the JECFA report, which had just become available. JECFA estimated on the basis of positive human epidemiological studies, two potencies for human liver cancer covering a broad range of possible values applicable to individuals without hepatitis B infection and to individuals with chronic hepatitis B infection (HBsAg $^{+}$) respectively. Furthermore, by applying hypothetical standards for aflatoxins in food, the population risk for model populations was calculated i.e. populations with a low and a high prevalence of HBsAg $^{+}$.

The Rapporteur noted that, in making this evaluation, JECFA had neither proposed nor endorsed any population risk-level or aflatoxin contamination level of as being acceptable.

Extensive discussion led to the following opinion:

The SCF last considered the human toxicology of aflatoxins in its opinion on aflatoxins, ochratoxin A and patulin expressed on 23 September 1994 (35 th Report Series). At that time the SCF concluded, inter alia,:

- *- "Aflatoxins are genotoxic carcinogens. For this type of carcinogen, it is generally felt that there is no threshold dose below which no tumour formation would occur. In other words, only a zero level of exposure will result in no risk.*
- *- It agreed with the recent evaluations of IARC (2) (1993) with respect to the carcinogenicity and genotoxicity of the aflatoxins. From the many reports on risk assessment, it can be concluded that even very low levels of exposure to aflatoxins, i.e. 1 ng/kg b.w./day or less contribute to the risk of liver cancer."*

At the 49 th meeting, held in Rome, Italy from 17 to 26 June 1997, the JECFA $^{(3)}$ reviewed a wide range of studies in both animals and humans that provided qualitative and quantitative information on the hepatocarcinogenicity of aflatoxins.

The SCF discussed this recent JECFA evaluation merely on the basis of the summary report of the meeting. It noted that the background documentation which served as a basis for the JECFA evaluation has not been published yet and was not available for the SCF. The SCF therefore felt that it was not in the position to give a complete appraisal of the JECFA evaluation.

In the JECFA evaluation it is stated that the Committee (JECFA) considered that the weight of scientific evidence, which includes epidemiological data, laboratory animal studies and in vivo and in vitro metabolism studies, supports a conclusion that aflatoxins should be treated as carcinogenic food contaminants, the intake of which should be reduced to levels as low as reasonably achievable.

JECFA concluded, inter alia, that

- *- "Aflatoxins are considered to be liver carcinogens. Aflatoxin B_1 is the most potent carcinogen of the aflatoxins; most of the toxicological data available are related to aflatoxin B_1. Aflatoxin M_1, the hydroxylated metabolite of B_1, has a potency approximately one order of magnitude less than that of B_1."*
- *- "The Committee (JECFA) has previously noted that reductions can be achieved through avoidance measures such as improved farming and proper storage practices and/or through enforcing standards for food or feed within countries and across borders (WHO Technical Report Series N° 759, 1987)."*

These statements are not incompatible with the SCF's opinion expressed in 1994, which remains valid.

The SCF recognises the great effort made by JECFA to perform a quantitative risk assessment by combining carcinogenic potencies and human exposure data, but noted also the several limitations and assumptions, inherent in this approach, which were clearly set out in the report.

The SCF concluded that, given its present state of knowledge in this area, it was not possible to assess the degree of uncertainty, arising from these limitations and assumptions, in the quantitative risk assessment and felt therefore that it was premature for it to draw definitive conclusions on this issue.

(2 *)* International Agency for Research on Cancer

(3) Joint FAO/WHO Expert Committee on Food Additives

16. Food Microbiology and Hygiene

16.1 Adoption of an opinion on the potential microbiological risk arising from the presence of moisture in tea

The Chairman of the Working Group introduced the opinion and explained that the Committee had been asked to advise the Commission on the potential micro-biological risk associated with the presence of moisture in tea and to indicate in general terms, an acceptable upper limit from the view point of public health. The opinion was adopted with the following conclusion:

In 1995, the FAO (Food and Agricultural Organisation) international group established a standard on black tea (1). This standard includes a paragraph specifically on moisture content and states that tea should be packed with a moisture content of less than 4 percent. The document also states that it is likely that during transport to the point of export and further shipment to the importing country, tea absorbs more moisture and that tea with a moisture content of 6 percent and above deteriorates in quality.

Tea has a long history of safe use and the Committee is not aware of any safety problems related to moisture in tea. This may be attributed to low moisture content (i.e. water activity) and the high content of anti-microbial substances. Moisture levels of up to 10% seem to give an acceptable safety margin for the storage of tea. A lower level may be needed in order to restrict quality defects.

However, a general review is recommended for acceptable levels of water in low moisture foods. Assessment of acceptable levels should focus on potential growth of mycotoxicogenic moulds. Acceptable levels should be based on water activity (A_w) and follow the general principles for safe storage.

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

16.2 Discussion paper on microbial resistance in food-borne organisms

The Chairman of the working group explained that the paper had been developed as a means of drawing the Commission's attention to the urgent need to give detailed consideration to the general question of microbial antibiotic resistance. Although the question had arisen in the context of risks of microbial resistance arising through food consumption, the problem was of relevance in other fields such as pharmaceuticals, animal nutrition and medicine.

Members welcomed the paper and fully supported the importance of the problem.

The Committee therefore drew the attention of the Commission to potential risks to public health arising from increasing antibiotic resistance. In so doing it recognises the multi-disciplinary nature of the problem and suggests that it may be considered by the Scientific Steering Committee.

16.3 Gamma irradiation of egg and egg products

The Committee had previously evaluated the safety of the irradiation of certain foods in its Opinion expressed on 13 th March 1986 (Report on the Irradiation of Foods; Report of the SCF, 18 th Series). This identifies overall average radiation doses for certain classes of foods (fruits, vegetables, cereals, starchy tubers, spices and condiments, fish and shell fish, fresh meats and poultry), but not for egg and egg constituents. The Report allowed for the extension of the classes of foods, where information is given to the Committee so that thorough evaluation can be undertaken.

Following consideration of information provided to the Committee on the irradiation of egg and egg constituents, the Committee concludes that the petitioner has not provided sufficient data in relation to toxicological and radiation-chemical studies to demonstrate the absence of toxicity following irradiation, and further, that the studies were inadequate to demonstrate the efficiency of the process.

The Committee was concerned about the poor hygienic quality of the egg and egg constituents as evidenced by their high initial bacterial counts.

It was concluded that the dossier be rejected and the petitioner requested to re-submit it in accordance with the Report of the SCF on the irradiation of food expressed on 13 th March 1986.

16.4 Use of Papain as a meat tenderiser

The Working group chairman introduced the draft opinion and recalled that in its opinion on Papain from Papaya Fruit (Carica papaya) used as a Meat Tenderising Agent, expressed in June 1995, the Committee had considered that the use of papain as a meat tenderiser, administered to stunned and pithed animals before bleeding, was acceptable from the point of view of the safety of papain *per se*, provided the general provisions of the guidelines on enzymes were followed.

In that opinion, the SCF also considered that the bacteriological safety of meat, where papain is injected into beef as a meat tenderiser, should be confirmed by pilot testing under different conditions, representative of actual hygiene conditions in slaughterhouses in different Member States of the EU. In its 1995 opinion, the Committee raised the question of whether the use of papain-treated meat in fermented sausages might affect the levels of biogenic amines in the final product.

The petitioner subsequently submitted further information for evaluation by the SCF to address the concerns raised in the 1995 opinion.

The Committee concluded as follows.

The Committee remains concerned about the microbiological safety of the meat injected with papain under slaughterhouse conditions, particularly in relation to the increased risk of contamination through the injection site and the subsequent risk of propagation of micro-organisms into other parts of the body. The Committee is also concerned that the delay in bleeding necessary to facilitate the spread of papain throughout the body, may increase the opportunity for micro-organisms introduced in the way outlined above or in the papain solution itself, to be disseminated. The Committee recommends that the issues raised relating to veterinary hygiene in slaughterhouses and in particular to the pithing and other processes involving the introduction of materials into deep tissue layers are examined by the Scientific Committee on Veterinary Measures relating to Public Health.

In its 1995 opinion, the Committee raised the question of whether the use of papain-treated meat in fermented sausages might affect the levels of bio-genic amines in the final product. After consideration of the information provided in the report submitted by the applicant, the Committee was not able to draw a firm conclusion on the likelihood of an increase in amine production after papain treatment, but such an effect could not be excluded.

In these circumstances, the Committee is unable to give a favourable opinion on the use of papain as a meat tenderiser, injected after stunning and before bleeding under slaughterhouse conditions

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

17. Intake and Exposure

No matters were raised

18. Scientific Co-operation

No matters were raised

19. Any other business

In the light of difficulties encountered with certain recent dossiers, the Committee wished to make it clear to petitioners that it expects all available relevant studies and information to be submitted to it. Failure to do so may lead to rejection, delay, incomplete or even invalid risk assessment conclusions

Members took the opportunity of the final meeting of the Committee prior to the reorganisation of the Commission's scientific Committees to express their appreciation of Prof. Pascal's excellent chairmanship, patience and guidance though many difficult issues. Prof. Pascal in turn thanked the Members of the Committee and the Secretariat for the high level of support he had received and stressed that adequate Secretariat staffing was essential if the Committee was to continue to deal with urgent matters of public health in a timely and efficient manner.

The Minutes were adopted by a written procedure.