MAFF

DEPARTMENT OF HEALTH

ACNFP ANNUAL REPORT 1994

Ministry of Agriculture, Fisheries and Food
and
Department of Health

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The Advisory Committee on Novel Foods and Processes (ACNFP) is an independent body of experts whose remit is:

'to advise Health and Agriculture Ministers of Great Britain and the Heads of the Departments of Health and Social Services and Agriculture for Northern Ireland on any matters relating to the irradiation of food or to the manufacture of novel foods or foods produced by novel processes having regard where appropriate to the views of relevant expert bodies'.

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FOREWORD

This sixth Annual Report shows substantial progress on two new approaches to safety evaluation and gives details of the ACNFP's evaluation of three GM plant products. The two approaches – consideration of safety issues arising from the use of antibiotic resistance markers, and the use of a systematic approach to the safety assessment of novel foods and processes – draw from our experience of the last six years and have involved widespread consultation. This dual approach – learning from experience and consulting widely – is typical of the work of our Committee. Both processes are designed to make clear to all those interested just how the regulatory process is working, and we believe this approach to be of value to both companies and consumers.

The three plant products are the first major new products to come on to the British market as a result of the use of genetic modification. The products represent three major crops – tomatoes, oilseed rape and soya beans. In each case sophisticated new technology has been used to improve the quality or yield of a widely used plant product. We believe that these products are certainly as safe as their conventional counterparts, and that they will come into safe general use.

DEREK C BURKE
(Chairman)

INTRODUCTION

This is the sixth annual report of the work of the ACNFP. It covers the specific issues discussed at the Committee meetings held during 1994, together with details of related topics which were brought to the Committee's attention. Some of the topics discussed during 1994 were continuations of previous work while others were original. For completeness, topics which were not discussed in 1994 but have data requests outstanding from previous years are identified. Brief details of the Committee's reviews of products and processes are included in the body of the report. The advice given to Ministers and other detailed material are presented in Appendices.

The organisation, remit and membership of the Committee are set out at Appendix 1.

Copies of previous annual reports [1,2,3,4,5] can be obtained from the Administrative Secretary (see page 14). A cumulative index of all topics considered in the annual reports may be found at the back of this document (page 92).

Technical terms which are not explained in the body of the report are underlined where they appear for the first time in the text and are explained in the glossary (page 17).

1. TOPICS CONSIDERED AND FINALISED DURING 1994

1.1 ANTIBIOTIC RESISTANCE MARKERS

In July 1994 the ACNFP published a report on the use of antibiotic resistance markers in genetically modified food organisms [6]. This topic has been discussed in previous annual reports [2,3,4,5]. *Genetic modification* procedures often use *genes* which confer resistance to *antibiotics* such as kanamycin and neomycin as a means of selecting modified organisms. If the insertion is successful, then the modified organism will survive and grow when cultured in the presence of the antibiotic; unmodified organisms will die or exhibit restricted growth. Concern has been expressed that the use of such markers may compromise the clinical effectiveness of the antibiotics due to transfer of the resistance from the genetically modified food organism to *pathogenic* bacteria.

In its report the ACNFP identified four possible food safety problems which might arise from the use of antibiotic resistance markers. These are

(i) any inherent toxicity of the marker gene

(ii) transfer into and expression of the marker gene in gut epithelial cells and/or gut *micro-organisms*

(iii) allergenicity of the gene product

(v) inactivation of anti-microbials, such as nisin, by the gene product.

The Committee concluded that only one of these potential problems, the possibility of transfer and subsequent expression of marker genes in gut micro-organisms, is of significance. However, the possibility of such a transfer and expression occurring was considered to be extremely low and the Committee view was that if it were to occur, it is most likely from live genetically modified food bacteria used as starter cultures or *probiotics*.

The report contains a number of recommendations on the use of antibiotic resistance markers in *viable* and non-viable food micro-organisms and plants and encourages the development of alternatives to these markers.

A copy of the report can be obtained from the Administrative Secretary (see page 14).

1.2 TOMATO PASTE FROM GENETICALLY MODIFIED TOMATOES

In tomatoes, as in many other foods, the *enzyme* polygalacturonase (PG) is responsible for the breakdown of the cell wall and the intracellular component pectin during ripening which leads to softening and ultimately the disintegration of the tomato. In 1994 the Committee received a submission requesting food safety clearance of tomato paste derived from a commercial tomato *cultivar* which had been genetically modified to slow down the synthesis of the PG enzyme. Lower enzyme levels enable the fruit to ripen normally but soften less quickly, thereby extending the life of the ripe fruit so that it can be vine-ripened for longer than

existing conventionally bred varieties before harvest. As a result of this the modified tomatoes, with their increased levels of the natural thickening agent pectin, possess the desired processing qualities for tomato paste manufacture.

The reduction in synthesis of the PG enzyme was achieved by inserting a *truncated PG gene* isolated from a common garden tomato variety (*Lycopersicon esculentum* Mill var. 'Ailsa Craig') into a commercial *inbred line* of a processing tomato identified as TGT7. As an aid to selecting successfully modified tomatoes, a gene conferring resistance to certain antibiotics was also introduced.

In assessing the safety of the tomato paste produced from the genetically modified (GM) tomatoes the ACNFP evaluated comparative data on the nutritional and toxicological parameters of the tomato paste derived from the GM tomatoes and tomato paste produced from similar but unmodified, conventionally bred tomatoes. The Committee also focused upon the safety of the intentional changes and identification of any unintended changes resulting from the modification. The stability of the genetically modified tomatoes under the intended conditions of use, the likelihood of transfer of genetic material from the paste to human consumers and human exposure data were also considered.

The Committee was satisfied that the novel genes had been effectively and stably integrated and concluded that, except for the specific intended effects of the introduced genes, there were no agronomic or compositional differences between the modified tomatoes and pastes produced from them and their conventional counterparts.

The Committee recognised that there is no inherent toxicity associated with either of the introduced genes or their enzyme products and that these would not in any case survive the processing conditions. Furthermore, even if the genes or their products were to be ingested they would be rapidly destroyed by the digestive enzymes.

The ACNFP concluded that tomato paste derived from the GM tomatoes is as safe for human consumption as tomato paste derived from conventionally bred tomatoes currently consumed as part of the UK diet. The Committee recommended food safety clearance of the paste, provided that it complies with the Codex specification for tomato paste concentrates. Additionally, the Committee was pleased to note that the company had agreed to its request that appropriate data should be provided at regular intervals to confirm the long-term stability of the GM lines.

Clearance of fresh GM tomatoes was not sought. The ACNFP concurred that this would require a separate submission to the Committee.

This advice, which is reproduced in Appendix 2, was passed to Ministers who announced clearance of the tomato paste on 20th February 1995.

1.3 OIL FROM GENETICALLY MODIFIED OILSEED RAPE

When two plants of the same species are crossed, the resultant *progeny* may sometimes show *hybrid vigour* and surpass both parents in characteristics such as growth rate, size or yield. In order to grow crops which show hybrid vigour, plant breeders produce hybrid varieties. With self-pollinating plants, the production of

hybrid varieties is achieved by developing separate 'male' and 'female' lines. The 'female' line does not produce active pollen and will not self-pollinate, it is *male sterile*. The 'male' line produces active pollen and is used to pollinate the 'female' line. The 'male' line also carries a fertility restorer gene which ensures that plants grown from the hybrid seed are male fertile and will develop seed normally.

In 1994, the ACNFP received a request for food safety clearance of oil from oilseed rape that had been genetically modified for use in a breeding programme for the production of hybrid seed. The production of hybrid oilseed rape varieties has been difficult because the use of naturally occurring male sterility has proved unsatisfactory. However, genetically modified male sterile and fertility restorer lines were developed through the introduction of two bacterial genes. *Marker genes* conferring antibiotic resistance and *herbicide* tolerance were used as selection aids in the modification procedure.

The GM lines developed from the original *transformants* were used to produce a number of male sterile and fertility restorer lines for use in hybrid seed production by conventional breeding with commercial oilseed rape varieties.

In assessing the safety of oil produced from the GM oilseed rape, the ACNFP compared compositional data on oil from the GM lines and hybrids with that on oil from conventionally bred commercial varieties. The Committee also considered data on the processing characteristics of the seed from the GM lines and hybrids. The products of the introduced genes, including the marker genes, are not found in the seed and are therefore not present in oil derived from these seeds. The ACNFP was satisfied that, compositionally, there was no difference between oil from the GM and conventionally bred oilseed rape.

The Committee also examined information on the modification procedure used, data to show that the introduced genes were inherited stably and the results of field trials which demonstrated that there had been no unintended effects on the agronomic traits of the GM oilseed rape.

The ACNFP concluded that oil from the GM oilseed rape was as safe as that obtained from conventionally bred rape and recommended clearance of the oil for human food use, provided that it complies with Codex and other internationally agreed standards used in the trade of oils and fats. The Committee asked that further compositional data be submitted at regular intervals to confirm the long-term stability of the GM oilseed rape. The company has agreed to provide this information.

A marketing consent under the UK legislation implementing the Deliberate Release Directive 90/220/EEC is required for the GM oilseed rape. A report of the ACNFP's advice to Ministers is attached at Appendix 3. Clearance of the oil for food use was announced by Ministers on 20th February 1995.

1.4 HERBICIDE TOLERANT SOYA BEANS

Soya beans and soya bean fractions are used in a wide range of food products. In 1994 the Committee received a request for clearance of soya beans derived from plants genetically modified to be tolerant to the herbicide glyphosate. Clearance was also sought for soya beans from glyphosate tolerant soya bean (GTS) lines

derived from crosses of the original GM line with commercial soya bean cultivars. Glyphosate works by inactivating an enzyme in the plant which is essential for the production of complex amino acids; thereby preventing growth. Glyphosate tolerance was achieved through the introduction of a gene from a bacterium (*Agrobacterium* sp.) into a commercial soya bean cultivar (*Glycine max*). This gene codes for an enzyme which has the same function as the glyphosate-sensitive enzyme in the plant but is not itself inhibited by glyphosate. The bacterial form of the enzyme therefore remains active in the presence of glyphosate when the plant enzyme is inhibited.

An enzymic marker gene was introduced into the modified soya bean plant along with the gene conferring glyphosate tolerance. Expression of enzymic marker gene was used as an indication that the modification procedure had been successful. During conventional propagation of the GM soya bean plant this marker gene was lost through normal genetic segregation. The GM soya bean line (40-3-2), for which clearance is sought, contains only the gene conferring glyphosate tolerance.

The Committee considered the data submitted, which covered aspects relating to the development, selection and safety of the modified soya beans and products derived from them. The approach taken by the ACNFP in its safety assessment was to compare the GTS beans, and products derived from them, with their conventional counterparts. The Committee concluded that the composition and nutritional value of the GTS beans were equivalent to that of unmodified soya beans. Soya beans are known to give rise to an *allergic reaction* but the ACNFP was satisfied that the allergenic potential of the modified beans was no greater than that of conventional soya beans.

The Committee was satisfied that the bacterial enzyme, which is present at very low levels in the soya beans (<0.1% of the total soya bean protein), did not present a food safety hazard. It also concluded that the potential for genetic transfer to humans and/or their gut microflora was negligible since soya beans were not consumed unprocessed because they naturally contain certain factors which may be toxic if not destroyed by heating during preparation.

The ACNFP concluded that the GTS beans and products derived from them are as safe for human consumption as other conventional soya bean strains and products derived from them. The Committee recommended clearance of the GM soya beans provided that all soya products derived from them meet the appropriate existing specifications. The company has agreed to the Committee's request that compositional data on the GM soya beans be provided at regular intervals in order to confirm the long-term stability of the GM beans.

Importation of viable GM soya beans into the UK would require a marketing consent under the UK legislation implementing the Deliberate Release Directive 90/220/EEC. Soya beans are not widely grown in the UK but any beans treated with glyphosate should comply with UK, EC or Codex Maximum Residue Levels (MRLs).

Ministers announced clearance of glyphosate tolerant soya beans and products derived from them for food use on 20th February. A copy of the ACNFP report on the modified soya beans is attached at Appendix 4.

2. TOPICS ABOUT WHICH THE COMMITTEE HAS NOT CONCLUDED ITS DELIBERATIONS

The ACNFP tries to process submissions with the minimum of delay without compromising the quality of the safety assessment. However, there are times when advice needs to be sought from other Committees or proposers need to perform further studies to provide more data. In such cases the ACNFP is not able to reach final conclusions until further advice or new data are available.

2.1 REQUESTS OUTSTANDING FROM PREVIOUS YEARS

In certain instances proposers may need over a year to generate the data requested by the ACNFP or sister Committees. Additional data requested by the Committee in previous years on the topics listed below remained outstanding. However, the proposers involved have indicated that they will be acting on the requests for further data but that it may take some time. Further details may be found in the appropriate ACNFP annual reports.

(i) Lupins and lupin fibre [2,3,4]

(ii) Quinoa [2,3,4]

(iii) Sugar beet fibre [4]

(iv) Mycelial protein from *Polyporus squamosus* [5]

(v) Guarana [5]

(vi) Interesterified fats for infant formulae [4,5]

2.2 *BACILLUS LATEROSPORUS*

A submission requesting clearance for the use of a strain of *B. laterosporus var. bod* as a probiotic was considered by the ACNFP in 1993 [5]. The Committee considered that the submission provided inadequate data to enable the safety-in-use of the product to be assessed and further information was requested from the company. The company has subsequently indicated that it wished to withdraw the submission.

2.3 LIPASE ex *ASPERGILLUS ORYZAE*

This enzyme was referred by the ACNFP to the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) for safety assessment. The COT considered lipase ex *Aspergillus oryzae* during 1994 and requested that further data be submitted. Some, but not all, of the data requested have been submitted. The outstanding data are awaited.

2.4 NOVEL CONFECTIONERY FAT TO REPLACE COCOA BUTTER

Further data on a previously identified area of concern was submitted to the ACNFP in 1994. Due to a number of unsatisfactory aspects in the data, the Committee has asked for an additional study in this area. The ACNFP noted that changing dietary lipids can have an effect on thrombotic potential, therefore the Committee also looked at the generic question of assessing novel fats for possible effects on thrombotic potential.

3. PROGRESS ON TOPICS CONSIDERED PREVIOUSLY

3.1 FOOD USE OF ANIMALS FROM TRANSGENIC BREEDING PROGRAMMES

Subsequent to the report of the Committee on the Ethics of Genetic Modification and Food Use, the ACNFP considered a submission requesting clearance for the release of certain classes of animals involved in a transgenic breeding programme into the food chain. The breeding programme is intended to provide compatible organs for human transplant purposes. The animals in question are not transgenic, that is they do not contain any foreign genes. The Committee agreed that the proposal to release these animals into the food chain did not raise any particular food safety or ethical concerns. The advice of the Food Advisory Committee (FAC) was sought on labelling aspects. The FAC's view was that such animals should not enter the food chain (see FAC Annual Report 1994). The company involved subsequently withdrew its submission.

4. OTHER ACTIVITIES

4.1 STRUCTURED APPROACH TO THE SAFETY ASSESSMENT OF NOVEL FOODS AND PROCESSES

In 1991 the ACNFP published guidelines on the assessment of novel foods [7]. Since then the Committee has gained much experience from assessing submissions and through contacts with industry and other agencies, including international agencies. The Committee was eager that this experience be used to refine and expand the guidelines. Therefore, in 1993 the ACNFP established a working group to examine the possibility of developing a set of procedures, based on 'HAZOP-type' principles, for assessing the safety of novel foods and processes [5]. HAZOP (Hazard and Operability studies) is used by the chemical industry to characterise potential hazards; it involves investigating, via sequences of linked questions, the possible outcomes of a failure of a component or alteration to a specific part of a chemical plant or process.

In May 1994 the Committee considered and endorsed the working group's recommendations that the existing ACNFP decision tree found in the guidelines should be modified and that a series of structured questionnaires should be developed for each of the information requirements associated with the exit points of the decision tree. A Committee paper entitled 'A Structured Approach for the Safety Assessment of Novel Foods and Processes: Revision to Chapter 4 of the ACNFP's Guidelines' detailing the proposed changes was issued for public consultation in July 1994. The consultation period ended on 7th October 1994.

The consultation document emphasised that the Committee's decision tree approach is intended to be applied flexibly with each submission made to the Committee considered on its merits and evaluated on a case-by-case basis. This flexibility is seen as an integral aspect to the safety assessment of the range of novel foods which are expected to approach commercialisation in the future as a result of the rapid and new developments in biotechnology.

Comments were received from a number of interested parties including industry, consumer groups, research institutes, professional associations, and international agencies. In general, most organisations welcomed the new structured approach as a valuable aid in indicating the level of detailed safety data likely to be needed prior to any submission to the ACNFP.

A copy of the new structured approach is attached at Appendix 5. This new approach replaces the decision tree published in the 1991 ACNFP Guidelines and can be used to assist companies in compiling their submissions to the Committee. It is the Committee's ultimate aim to incorporate the structured questionnaires in a revised edition of its guidelines to be published at a future date. However, some minor revisions may be required in light of experience and developments elsewhere when the charts are incorporated into a future edition of the ACNFP's Guidelines.

A copy of the new structured approach can also be obtained from the Administrative Secretary (see page 14).

5. DEVELOPMENTS ELSEWHERE

5.1 EUROPEAN COMMISSION PROPOSAL FOR A REGULATION ON NOVEL FOODS

The controls on and assessments of novel foods vary between the Member States of the European Union and in an effort to introduce a harmonised approach the European Commission (EC) developed proposals for a Regulation on novel foods and novel food ingredients, the first draft of which was published in July 1992 [8]. Since then various meetings have been held and revised versions of the text produced; the latest version is the ninth but full agreement of all Member States has still not been reached.

Discussions continued in 1994 under the Greek presidency and a common position was sought but not reached at the Internal Market Council (IMC) meeting on 16 June 1994. Further discussion took place under the German presidency. However, very little progress was made. The main issue still to be resolved is that of labelling, particularly that of GMOs. The UK position has been to follow the advice given by the FAC that labelling should be considered on a case-by-case basis and that mandatory labelling should only be required for those foods containing 'ethically sensitive' copy genes. However, some other Member States have insisted on more extensive labelling.

The French are expected to progress this proposal further under their term of presidency in 1995 and details of the current position can be obtained from the Administrative Secretary (see page 14).

5.2 EUROPEAN COMMISSION PROPOSAL FOR A DIRECTIVE ON FOOD IRRADIATION

In December 1988 the EC published a proposal for a Council Directive (COMM(88)654) on foods and food ingredients treated with ionising radiation [10]. However, despite early agreement on the technical controls in the proposal, because of the range of attitudes to food irradiation that exist in individual Member States it has not been possible to reach agreement on the range of foods to be approved for treatment at community level and discussions have been deadlocked.

The proposal was last considered briefly by Member States of the EU in 1992, but was unexpectedly raised by the German presidency at a Council Working Party meeting on 7 November 1994. A draft amendment proposing compromise solutions to the outstanding issues was tabled for discussion. A further meeting was held on 23 November where the discussions centred on a proposal to split the directive into two to give an implementing [11] and a framework directive [12]. The implementing directive would establish a Community list of foods that may be treated with ionising radiation, together with the maximum doses authorised for the intended purpose. At present only dried aromatic herbs, spices and vegetable seasonings are included, but a provision is included whereby this list can be extended. The framework directive would set out the general provisions for the manufacture, marketing and importation of foods and food ingredients treated with ionising radiation, including items such as labelling, authorisation or irradiation facilities and amendment of any existing national authorisations.

Although the approach of considering two directives found general support, little progress was made on the detail of the two directives.

Details of the current position can be obtained from the Administrative Secretary (see page 14).

5.3 OECD WORKSHOP ON FOOD SAFETY EVALUATION

In 1993 the Organisation for Economic Cooperation and Development (OECD) published a report on the safety evaluation of foods derived by modern biotechnology [13] which recommended that the most practical approach in determining the safety of such novel foods was to consider whether the new food was substantially equivalent to analogous conventional foods, if such food existed. In September 1994, the OECD held a workshop to examine the question of what strategies could be used to establish the safety of novel foods produced by biotechnology when there was no acceptable counterpart for comparison.

The workshop reviewed current methods used in the safety evaluation of new foods and considered specific case studies. A sequential approach was recommended to determine the appropriate testing strategy for a new food, based on the properties of the food. Analytical studies would provide the starting point for the safety assessment. Data on chemical composition of the food should be used to determine what further studies were necessary. The workshop noted that databases could provide valuable baseline information on nutrients and toxicants and could be used to assess the significance of any changes in these components.

The need for toxicology studies on new foods would be established on a case-by-case basis but they would generally not be required. However, if animal testing was necessary then the objectives of the testing must be clear. The workshop discussed the difficulties in the testing of whole foods, where nutritional imbalance may mask toxic effects and encouraged the use of properly validated *in vitro* test systems. Consideration of the testing of extracts and specific components of whole foods was recommended but it was conceded that this too had its limitations. It was agreed that human studies were generally not recommended but that such studies may be appropriate in cases where specific groups in the population may metabolise a novel food differently to the general population.

It is anticipated that a report of the workshop will be published later this year.

5.4 WHO WORKSHOP ON THE APPLICATION OF THE PRINCIPLES OF SUBSTANTIAL EQUIVALENCE TO THE SAFETY EVALUATION OF FOODS OR FOOD COMPONENTS FROM PLANTS DERIVED BY MODERN BIOTECHNOLOGY

The ACNFP uses a comparative approach when assessing the safety of a novel food for which there is an existing, similar food which is known to have an acceptable standard of safety. This has been most apparent in the Committee's safety evaluation of products from GM plants where these products were compared with those from conventionally bred plants.

The concept lying behind this comparative approach has been developed by the FAO/WHO and formalised by the OECD as the 'concept of substantial equivalence'. A WHO workshop, hosted by the National Food Agency of Denmark, was held in November 1994 to provide practical guidance in the way in which the concept of substantial equivalence could be applied in evaluating the safety of foods or food components from plants derived by modern biotechnology.

The WHO Workshop used a number of case studies as the basis for its considerations, including a summary of the way in which the ACNFP had evaluated the safety of oil from GM oilseed rape. Discussion among participants concluded that the determination of substantial equivalence entails a consideration of the molecular characterisation of the new plant line, its agronomic traits and critical nutrients and toxicants present. The Workshop also identified factors that should be taken into account in the identification of suitable reference characteristics and the need for such characteristics to be flexible over time to accommodate changes demanded by processors and consumers.

It is anticipated that the report of the Workshop will be published before summer 1995.

6. CONTACT POINTS

For further information about the general work of the Committee, contact in the first instance:

The Administrative Secretary,
Mr Nick Tomlinson,
Ministry of Agriculture, Fisheries and Food,
Room 425, Ergon House,
c/o Noble House,
17 Smith Square,
London SWIP 3JR.

Information about specific scientific points or concerning individual submissions (which have been made or are being contemplated) may be obtained by contacting:

The Scientific Secretariat,
Ms Ranjini Rasaiah,
Ministry of Agriculture, Fisheries and Food,
Room 204, Ergon House,
c/o Noble House,
17 Smith Square,
London SWIP 3JR.

Queries relating specifically to safety matters may be addressed to the Medical Secretariat:

The Medical Secretariat,
Mrs Sue Hattersley
Department of Health,
Room 509A, Skipton House,
80 London Road,
London SE1 6LW.

7. REFERENCES

1. Advisory Committee on Novel Foods and Processes. *Annual Report 1989*. Department of Health and Ministry of Agriculture, Fisheries and Food, 1990. (Available from the ACNFP Secretariat).

2. Advisory Committee on Novel Foods and Processes. *Annual Report 1990*. Department of Health and Ministry of Agriculture, Fisheries and Food, 1991. (Available from the ACNFP Secretariat).

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5. Advisory Committee on Novel Foods and Processes. *Annual Report 1993*. Department of Health and Ministry of Agriculture, Fisheries and Food, 1994. (Available from the ACNFP Secretariat).

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7. Department of Health. *Guidelines on the Assessment of Novel Foods and Processes*. London. HMSO, 1991. (Report on Health and Social Subjects; 38).

8. European Commission. *Proposal for a Council Regulation (EEC) on novel foods and novel food ingredients*. Official Journal of the European Communities, No. C/190/3 of 27 July 1992.

9. European Commission. *Amended proposal for a European Parliament and Council Regulation (EC) on novel foods and novel food ingredients*. 11136/1/94 Rev 1, 5 December 1994.

10. European Commission. *Proposal for a Council Directive on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation*. Official Journal of the European Communities No. C336/7 of 31 December 1988.

11. European Commission. *Amended proposal for a European Parliament and Council Directive on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation.* . Presidency non-paper 11351/94 (Annex II).

12. European Commission. *Amended proposal for a European Parliament and Council Directive on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation*. Presidency non-paper 11351/94 (Annex I).

13. Organisation for Economic Co-operation and Development. *Safety Evaluation of Foods derived by Modern Biotechnology: Concepts and Principles*. Paris. OECD, 1993.

The Committee requests that unpublished sections of a submission are deposited with the British Library, in line with its views on the publication of available safety data. These depositions are identified in Committee reports by 'SUP Numbers' and may be obtained by contacting the British Library Document Supply Centre, Boston Spa, Wetherby LS23 7BQ.

8. GLOSSARY

allergic reaction: an altered or abnormal tissue reaction which may be caused by contact between a foreign protein, the allergen, and sensitive body tissues. The reactions may include nettle-rash, hayfever, asthma and dyspepsia.

antibiotic: a substance, usually derived from micro-organisms (e.g. bacterium) that destroys or inhibits the growth of other micro-organisms. Many antibiotics are used as drugs in treating disease.

cultivar: a variety produced by selective breeding.

enzyme: a protein produced by a living organism that changes the rate of, or promotes, a biological or chemical reaction without itself being altered or destroyed.

gene: unit of heredity composed of DNA, which forms part of a chromosome. The genetic code in a gene usually holds instructions for the manufacture of one polypeptide (protein) chain.

genetic modification: alteration of genetic material in an organism in a way that does not occur naturally by mating and/or natural recombination.

gut micro-organisms: micro-organisms living in the gut, sometimes termed 'gut microflora'.

herbicide: a compound which is capable of either killing or severely injuring plants.

hybrid vigour: when certain characters of the hybrid exceed the range displayed by its parents.

inbred line: a particular line of plant that has been self-pollinated over generations and is nearly genetically uniform.

male sterile: used as the 'female' parent in hybrid seed production, from which the hybrid seed is harvested. Only the female organs in the flowers are functional so that pollen must be obtained from other plants.

marker gene: a gene with a phenotype that can be selected for use in gene transfer experiments. Selectable genes are used to enable the selection/detection of neighbouring sequences in a gene construct.

pathogenic: capable of causing disease.

phenotype: the appearance or other characteristics of an organism resulting from the interaction between its genetic make-up and the environment.

probiotic: organism capable of colonising the gut of a higher organism and claimed to bring health benefits to the host.

progeny: offspring.

transformants: plants derived from transformed cells.

truncated PG gene: part of the PG gene which has been constructed *in vitro*.

viable: living matter capable of replication or of transferring genetic material.