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**ADVISORY COMMITTEE ON
NOVEL FOODS AND
PROCESSES (ACNFP)
ANNUAL REPORT
1997**

**Ministry of Agriculture, Fisheries and Food
and
Department of Health**

**ACNFP
ANNUAL REPORT
1997**

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 is the ninth annual report that the ACNFP has issued and the first under my Chairmanship which I took over from Professor Burke in 1997.

I cannot continue this short foreword without expressing a considerable debt of gratitude to Professor Burke for the substantial amount of work that he did both in leading the committee to its decisions and conveying those decisions and the depth of debate that underpins them to the public. Under his guidance the committee has made a considerable contribution to the way in which the safety of novel foods is considered across Europe.

The committee has an impressive membership with a wide variety of skills, including a consumer representative and ethicist, who play an active part in all deliberations thus ensuring a broader perspective.

The interaction and flow of information between advisory committees is important and in March 1998 the Chairs of these committees met to debate mechanisms for introducing transparency into their work. I am delighted that the ACNFP endorses the need for informed public debate and makes as much of its work as open as possible. We believe that with openness, and education of the public, we will engender confidence in our decision making, and ultimately in the fact that novel foods coming onto the UK market are safe for the consumer. In this context, one important generic issue that the committee is considering is the practicality of post market monitoring of genetically modified foods and an open meeting has been held when a wide range of consumer interest representatives observed the interchange between committee members and were given the opportunity to comment on it. The committee now publishes minutes of its meetings (from March 98). From May 1998 papers on which the committee bases its discussions will be available wherever possible.

In this transitional year, the committee has considered both applications made under the UK voluntary scheme (submitted before 15 May 1997) and also applications made under the Novel Foods Regulation, which puts into operation an EU-wide pre-market approval system for novel foods. The detailed procedures and time scales specified within the regulation have led to changes in the committee procedures. The safety assessment steps, common to all Member States, are based upon the decision tree approach very similar to the ACNFP's 1994 guidelines. The UK recognises the importance of enabling consumers to make informed choices and is pressing in Brussels for all foods approved under the Regulation which contain genetically modified material to be clearly labelled as a condition of approval.

The primary concern of the committee will continue to be the safety of the novel foods and processes submitted for assessment. We are committed to providing advice to government, responding effectively to industry and giving scientifically accurate and unbiased advice to the consumer. This report illustrates the extent and variety of the committee's work.

Clearly, public interest in the issues involved continues and I am committed to enhancing the committee's openness and to continuing the interchange with consumer groups, learned societies, the press and media.

INTRODUCTION

This is the ninth annual report of the Advisory Committee on Novel Foods and Processes (ACNFP) and the first report written since the EC Regulation on Novel Foods and Novel Food Ingredients (258/97) came into force on 15 May 1997. With the implementation of the Regulation the ACNFP has had to change both the way in which it works and the way in which it writes its annual report. Thus, the format of this ninth annual report is slightly different from that of previous reports. The first section of the report deals with the Novel Foods Regulation and its implications. Section 2 of the report contains updates on the evaluation of submissions made under the voluntary scheme for novel foods which operated in the UK prior to the implementation of the Novel Foods Regulation. These evaluations will not now be completed until the companies concerned make applications under the Novel Foods Regulation.

The ACNFP received five applications under the Novel Foods Regulation towards the end of 1997. Each of these was a request for an opinion on substantial equivalence of the novel food. Further details of these applications can be found in section 3 of the report.

The Committee also discussed a number of general issues during the year. These included consideration of the data required for an assessment of novel foods when no conventional counterparts exist and the dietary implications of cumulative nutritional changes in both novel and conventional foods. These issues are discussed in section 4 of the report.

The issue of labelling genetically modified (GM) foods was much debated during 1997 and the latest position on the European Commission's proposals for labelling GM soya and maize can be found in section 5 of the report. The report also contains an update on the progress of the EC Directive on Food Irradiation.

The Chairmanship of the ACNFP changed during 1997. After nine years as Chairman of the Committee, Professor Derek Burke retired from the role in August. The new Chairman is Professor Janet Bainbridge, Director of Science and Technology at the University of Teesside. Professor Bainbridge is a graduate in bacteriology and botany and has held a number of academic posts. Her particular research interests include nutrition, biotechnology and ethics.

Copies of previous annual reports¹⁻⁸ can be obtained from the MAFF Secretary (see page 17). A cumulative index of topics considered in previous annual reports can be found at the back of this report (page 42).

1. THE NOVEL FOODS REGULATION

1.1 THE REGULATION

On 15 May 1997, Regulation (EC) 258/97 of the European Parliament and of the Council concerning Novel Foods and Novel Food Ingredients⁹ came into effect introducing a statutory pre-market approval system for novel foods throughout the European Union. This Regulation is directly applicable and legally binding in all Member States, and in the UK replaced the voluntary scheme for the assessment of novel foods which had been in operation for more than 10 years. Companies now wishing to market a novel food in the EU are required to submit an application to the Competent Authority in the Member State where they first intend to market their product. In the UK the competent authority is provided by MAFF and the Department of Health working jointly but is likely to eventually be provided by the Food Standards Agency.

In the UK, the Novel Foods and Novel Food Ingredients Regulations 1997¹⁰ which came into effect on 16 June 1997, make provisions for the enforcement and execution of the EC Regulation in Great Britain, including offences and penalties. The Regulation will be enforced by food authorities as defined in the Food Safety Act 1990 and the Food Safety (Northern Ireland) Order 1991. To enable the cost of assessing applications to be recovered, Regulations¹¹ have been introduced setting out a scale of charges. This will be subject to periodic review. The cost for assessing an application involving a genetically modified organism (GMO),* for which an environmental risk assessment is required, is £6500. With such applications the advice of the Advisory Committee on Releases to the Environment (ACRE) is sought on the environmental risk assessment. For all other applications the cost is £4000 except for applications seeking an opinion on substantial equivalence which cost £1725.

The Regulation defines a novel food as food which has not been used for human consumption to a significant degree within the Community and which falls under one of the following categories;

- a. foods and food ingredients containing or consisting of GMOs within the meaning of Directive 90/220/EEC;
- b. foods and food ingredients produced from, but not containing GMOs;
- c. foods and food ingredients with a new or intentionally modified primary molecular structure;
- d. foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
- e. foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagation or breeding practices and having a history of safe food use;

*Technical terms not explained in the body of the report are underlined where they appear for the first time and are explained in the glossary; explanations are used in the context of the report and should not be taken as general definitions.

- f. foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

If there is any doubt whether a food is novel or not, the EC Standing Committee for Foodstuffs will make the final decision.

The Regulation acknowledges that for some novel foods and food ingredients their composition, nutritional value, intended use and level of undesirable substances may be substantially equivalent to conventional food ingredients. For food ingredients that fall into categories (b), (d) or (e) of the Regulation and are considered to be substantially equivalent to existing foods, the companies have the option of notifying the Commission when they first market the food product. However, this notification must be accompanied by evidence that the product is substantially equivalent to a conventional food. This evidence can be based either on the opinion of one Member State's Competent Authority or on generally available and recognized scientific evidence. Such foods are subject to the labelling requirements of the Regulation.

For all other novel foods, companies are required to submit an application to the appropriate Competent Authority in the Member State where they first intend to market the product. A copy of the application must also be sent to the Commission. Once the application has been accepted by the Competent Authority it has 90 days in which to complete an initial safety assessment and forward it to the Commission. The Commission must then copy the assessment to other Member States for their comments which have to be made within 60 days. If the initial assessment is favourable and no objections are raised by other Member States, then the food product can be marketed. If objections are raised, or if the initial Member State considers that an additional assessment is required, the application will be referred to the EC Standing Committee for Foodstuffs for final agreement, consulting the EC Scientific Committee for Food as necessary.

If agreement is not reached at the Standing Committee, the matter will be referred to the Council of Ministers. Here a qualified majority is required for the proposal to be agreed (a qualified majority is required in favour of a Commission proposal to accept or reject the application) or a unanimous vote in favour of amending the text if the proposal is to be changed. If neither of these situations occurs within 90 days of the proposal being put to the Council, it is deemed not to have acted and the Commission is free to implement it as it stands.

The Regulation allows a Member State to act when, as a result of new information or a reassessment of existing information, it has grounds for considering that the use of a novel food or food ingredient complying with the Regulation endangers human health. Member States may either temporarily restrict or suspend the trade in, and use of, that novel food. The Commission and other Member States must be informed of any such action and the grounds on which it was taken. The concerns will then be reviewed by the Standing Committee on Foodstuffs and appropriate action taken.

1.2 THE COMMISSION GUIDELINES

The Commission has published guidelines on the scientific information necessary to support applications for placing on the market of novel foods and novel food ingredients¹². These guidelines were prepared by the EC Scientific Committee for Food and are based on a decision tree approach similar to that used previously by the ACNFP. The guidelines identify six classes of novel food which differ in complexity and in the issues that need to be addressed;

- Class 1 Pure chemicals or simple mixtures from non-genetically modified (GM) sources;
- Class 2 Complex novel foods from non-GM sources;
- Class 3 GM plants and their products;
- Class 4 GM animals and their products;
- Class 5 GM micro-organisms and their products;
- Class 6 Foods produced using a novel process.

Each of the first 5 classes is also subdivided according to whether or not there is a history of consumption of the novel food source or host species in the case of GMOs. For each class of novel food, broad data requirements are identified in the guidelines which are refined by working through a series of questions. The ACNFP Secretariat has developed an interactive version of the Commission's decision tree to assist applicants in identifying the data required for their particular product. Copies can be obtained from the ACNFP Secretariat (see page 17).

The Commission guidelines also include instructions for companies on the presentation of information necessary to support applications and for Competent Authorities on the preparation of the initial assessment reports on applications.

1.3 IMPLICATIONS FOR THE ACNFP

The implementation of the Novel Foods Regulation and the new statutory procedures for the assessment of novel foods has brought changes to the way in which the ACNFP operates. In view of the short deadlines for carrying out an initial safety assessment (90 days) and for commenting on other Member State's assessments (60 days), the Committee has increased the number of meetings scheduled each year from 4 to 6 meetings. Nevertheless it is also envisaged that there will be times when deadlines for the completion of assessments fall between Committee meetings and therefore some of the evaluations will have to be carried out using the postal procedure developed by the Committee and Secretariat in recent years. The ACNFP has in the past had strong links with other advisory committees such as the Committee on Toxicity of Chemicals in Foods, Consumer Products and the Environment (COT) and the Committee on Medical Aspects of Food and Nutrition Policy (COMA). However, given the time constraints under which the ACNFP now has to operate it will no longer be possible for the Committee to refer submissions to these committees formally. The ACNFP is keen

to maintain its links with these Committees and thus a more informal approach has been developed whereby individual members of these committees or their sub-groups can be approached for advice on certain aspects of an application. When the Committee receives an application for a food or food ingredient that contains or consists of a GMO, the ACNFP will have to seek the advice of ACRE on the environmental risk assessment.

The ACNFP will continue to publish reports on its evaluations once the assessment procedures have been completed. Commission decisions on the authorisation of novel foods, which are based on the opinions of ACNFP and other Competent Authorities (or the Standing Committee for Foodstuffs) will be published in the Official Journal of the European Communities. The ACNFP will continue to encourage companies which make applications through the UK Competent Authority to deposit the accompanying dossier in the British Library.

2. APPLICATIONS MADE UNDER THE UK VOLUNTARY SCHEME

These applications were submitted to the ACNFP prior to 15 May 1997 and the evaluations had not been completed at that time. Whilst the Committee has provided advice on some aspects of these submissions, it cannot now provide a final opinion until an application has been received under the Novel Foods Regulation.

2.1 PROCESSED PRODUCTS DERIVED FROM GM TOMATOES

The ACNFP has previously considered submissions from Zeneca Plant Science seeking food safety clearance of tomato paste produced from certain lines of GM tomatoes. The tomatoes had been genetically modified to improve the fruit quality by reducing the levels of a pectin-degrading enzyme, polygalacturonase^{6,7}. In 1997, the Committee received a third submission seeking clearance of peeled and comminuted processed tomato products produced from hybrid lines derived from the GM inbred line TGT7-F. These hybrid lines had already been reviewed and cleared by the ACNFP for the production of tomato paste. Therefore, information pertaining to the genetic modification and the genetic stability of the introduced genes had not therefore been included in the data package on this occasion. The submission focused on nutritional and toxicological aspects.

The comminuted tomato products are derived using the same processing regime used to produce the tomato paste. The Committee had previously established the safety of both the fresh tomato derived from the hybrid lines and the tomato paste. It therefore focused its evaluation on peeled tomato products. Processing of peeled tomato products requires removal of the skin. This is achieved by steam/blanching or the use of infra-red radiation. Both processes involve temperatures in excess of 100°C. Peeled tomato products do contain seeds. However, the ACNFP reviewed the results of germination studies on seed taken from GM peeled and processed tomato products and from unprocessed GM and non-GM tomato fruits. The Committee was satisfied that under standard germination conditions the seeds from the processed product were incapable of germination.

The ACNFP considered data on the nutritional composition of the peeled products, the presence of naturally occurring toxins and the degradation of the aminoglycoside-3'-phosphotransferase (APH (3') II) protein produced by the nptII marker gene which is present in the GM tomatoes. The Committee was satisfied that the nutritional value of the peeled GM tomato products was similar to that of non-GM varieties and that the genetic modification had not altered the nutritional profile of the peeled tomato products. Analytical data on the levels of glycoalkaloids in both GM and non-GM peeled tomato products revealed these naturally occurring toxins to be below the level of detection. The Committee was also satisfied with data which indicated that the peeling and sterilisation process was sufficient to degrade the APH(3')II protein in the peeled GM tomato products.

The ACNFP concluded that peeled and comminuted products from GM tomatoes from hybrid lines derived from the GM inbred line TGT7-F were as safe for human consumption as those derived from non-GM tomatoes. However, as these products were not on sale in the EU prior to 15 May 1997, the company will need to seek approval under the Novel Foods Regulation before these products can be marketed in the EU. A copy of the Committee's report on the processed tomato products can be found at Appendix II.

2.2 STRUCTURED TRIGLYCERIDES COMPOSED OF MIXTURES OF SHORT CHAIN AND LONG CHAIN FATTY ACIDS

The ACNFP continued its evaluation of the data submitted on a family of structured triglycerides during 1997. The structured triglycerides are composed of mixtures of long and short chain fatty acids and are intended as low calorie fats for use in a variety of foodstuffs. The ACNFP had asked the COT for advice on the adequacy of the animal toxicology database on these novel fats and on the effects observed in the clinical safety studies on the fats. During 1997 a joint working group comprising selected members of the ACNFP and the COT met to consider the company response to the issues raised by both Committees on the toxicology data and the human studies, and to discuss the response with the company.

Although further information had been provided in the company's response, the working group considered that the information was deficient in a number of areas and indicated that further data would be needed. A statement containing the COT's advice on the areas it had been asked to consider was forwarded to the ACNFP in December. Details of the COT's advice can be found in the 1997 Annual Report of the Committees on Toxicology, Mutagenicity and Carcinogenicity of Chemicals in Food, Consumer Products and the Environment¹³.

The submission cannot be progressed further until the company has made a formal application under the Novel Foods Regulation.

2.3 LONG CHAIN POLYUNSATURATED FATTY ACID FOR USE IN INFANT FEEDING

In 1997, the ACNFP received a third submission seeking food safety clearance of an oil rich in the long chain polyunsaturated fatty acid (LCPFA), arachidonic acid, for use in infant formulas. The LCPFA is produced during the fermentation of the fungus *Mortierella alpina*. The ACNFP had sought the advice of the COT on the toxicology data submitted. The COT advised that further work was required to determine the cause of certain liver changes observed in a 90-day rat study on the LCPFA. Further data were submitted on this aspect towards the end of the year. However, the COT advised that these data did not identify the cause of the changes and that this issue still needed to be addressed.

Once again, this submission cannot be progressed until an application has been received under the Novel Foods Regulation.

2.4 LOW α -LINOLENIC FORM OF LINSEED

The ACNFP received a submission seeking food safety clearance of oil, oil-extracted meal, flour and whole seed from a variety of linseed or flax (*Linum usitatissimum*) that had been developed, using conventional plant breeding techniques, to contain low levels of the fatty acid α -linolenic acid. It was noted that the modified oil had a low content of vitamin E compared with the conventional oil and comparable oils. The oil from this new variety of linseed is expected to replace, in part, vegetable oils from sources such sunflower and safflower, and will be used for the same purposes as these oils i.e. domestic cooking and salad oils, commercial frying oil, margarines etc. Whole seed, flour and oil-extracted meal are likely to be included in bread and breakfast cereals and may replace linseed in other uses.

The ACNFP received the submission prior to the implementation of the Novel Foods Regulation. However, the company had indicated that it would be applying for clearance of the food ingredients from the new linseed variety under the Regulation. The ACNFP noted that the current European usage of oil from this source was approximately 30,000 tonnes p.a. and that margarines containing the oil are on sale in a number of different Member States. In view of this, it was suggested that food ingredients derived from this variety of linseed may not be considered a novel food within the meaning of the Novel Foods Regulation and the company was advised to seek further advice from the European Commission. The ACNFP also noted that article 4 of the Novel Foods Regulation stipulates that the applicant 'shall submit a request to the Member State in which the product is to be placed on the market for the first time'. From the information to ACNFP provided in the submission it appeared that oil was available in other Member States before it was launched in the UK.

Irrespective of whether food ingredients from this variety of linseed are considered to be novel or not, the ACNFP was concerned that the levels of α -linolenic acid had been reduced in the oil in order to improve shelf-life. In reducing the levels of this fatty acid to prevent rancidity, the ratios of n-3 to n-6 fatty acids were dramatically changed in the oil. The ACNFP was concerned that altering the fatty acid ratio in this way may have long-term effects on public health. The Committee acknowledged that this problem was not unique and that there is a growing trend in altering the fatty acid composition of vegetable oils, through the use of traditional plant breeding techniques, in order to improve their shelf-life but at the expense of nutritionally beneficial fatty acids. It was agreed that the generic question of the desirability of changing the composition of fats and oils in this way should be referred to COMA (see section 4.3).

2.5 EXTRACT OF PINE BARK

In May 1997, the ACNFP considered a submission seeking food safety clearance of an extract derived from the bark of the pine tree (*Pinus pinaster*). The extract contains a range of water soluble flavonoids which are reported to have both antioxidant and pro-oxidant properties. The extract is sold in the form of dietary supplements which have been on sale in the UK since 1990 and in the EU since 1987. In view of this, the ACNFP advised that supplements containing the extract would not be considered to be novel foods. However, the Committee was concerned about the toxicological implications of the data submitted and recommended that the submission be referred to the COT for its consideration.

2.6 POLYSACCHARIDE FAT REPLACERS

The ACNFP received a submission seeking clearance of a range of soluble and insoluble polysaccharides derived from cereals which are intended to be used as fat replacers. The polysaccharides are co-products produced from the same extraction process. Both of these materials can be used to replace fat in a range of foodstuffs. The insoluble polysaccharide material may also be used for fibre fortification of food. Although the polysaccharides can be obtained from a wide range of cereals, wheat and maize are expected to be the primary sources of these materials.

The Committee was generally content with the submission but asked for further information on how the polysaccharides behave in the gut. The submission cannot be progressed further until the company has made a formal application under the Novel Foods Regulation.

2.7 SINGLE CELL PROTEIN

The ACNFP began its consideration of a submission seeking clearance for a novel single cell protein in 1996. The protein is produced by the bacterial fermentation of natural gas and will be used as a raw material for the production of protein hydrolysates and autolysates. The ACNFP had referred the submission to the COT for advice on the toxicology data. The ACNFP considered the COT's advice at its meeting in February 1997 and accepted the COT's recommendation that further toxicology studies were required on the novel protein. The company was informed of this advice and is now carrying out further studies.

2.8 HEMICELLULASE ENZYME FROM GM *BACILLUS SUBTILIS*

The ACNFP was asked by the Food Advisory Committee (FAC) to provide advice on the genetic modification aspects of a submission seeking clearance for the use of a hemicellulase enzyme in breadmaking. This particular hemicellulase enzyme is derived from GM *Bacillus subtilis*. The ACNFP was content with the information provided on the genetic modification aspects and considered that there were no food safety concerns arising from the genetic modification procedures used.

Although the ACNFP had been asked to provide advice specifically on the genetic modification procedures, the Committee also discussed other aspects of the submission, including the information available on the production process and quality assurance aspects. The ACNFP was of the view that a detailed specification for the enzyme was required and that the company should be asked to provide either a product specification or a process specification to support the safety-in-use of the enzyme. The ACNFP requested that these comments be brought to the attention of the COT/FAC.

2.9 INSECT-PROTECTED GM MAIZE

In May 1997, the Committee received a submission seeking an opinion on the substantial equivalence of food products derived from a GM insect-protected maize line. The maize had been genetically modified for resistance to lepidopteran insect pests including the European corn borer. The modification was achieved by the introduction of a form of the *cryIA(c)* gene from *Bacillus thuringiensis*. The maize also contains a gene conferring tolerance to the herbicide glufosinate ammonium and several copies of a gene which confers resistance to the antibiotic ampicillin. The ACNFP requested further information on the degradation of DNA in processed maize products before it could reach an opinion on the maize. An application for approval of the maize will now have to be made under the Novel Foods Regulation.

3. APPLICATIONS MADE UNDER THE NOVEL FOODS REGULATION

3.1 HERBICIDE TOLERANT GM MAIZE

The ACNFP considered a submission from Dekalb Genetics Corporation, under the previous voluntary scheme for novel foods, seeking food safety clearance of maize that had been genetically modified to be tolerant to the herbicide glufosinate ammonium. Although the ACNFP had completed its evaluation by 15th May 1997 when the Novel Foods Regulation came into effect, its evaluation had not been submitted to Ministers for agreement of publication. The company was informed of this and decided to submit an application for clearance under the Novel Foods Regulation. An application was received towards the end of 1997 seeking an opinion on the substantial equivalence of the GM maize line DLL25.

The maize has been modified to be tolerant to the herbicide by the introduction of the *bar* gene, originally isolated from *Streptomyces hygroscopicus*, which encodes an enzyme, phosphinothricin acetyltransferase (PAT), which inactivates the herbicide. The maize also contains part of a gene which confers resistance to ampicillin. However, the gene is not functional as an incomplete coding sequence was incorporated into the maize genome.

The Committee used a comparative approach to consider whether ingredients from the GM maize were equivalent to ingredients from non-GM varieties. Compositional data provided to the Committee revealed no significant differences between the GM maize and its non-GM counterpart. However, GM maize sprayed with the herbicide had slightly higher levels of protein and oil than the unsprayed GM plants. This was attributed to the increased vigour of the plants. The data provided on the genetic modification procedure satisfied the Committee that no unintentional changes had taken place at the molecular level. Agronomic performance and segregation studies also satisfied the Committee that the introduced genes were integrated in a stable manner.

The Committee advised that as DNA and protein arising from the modification were present in certain processed maize products, the application could not be considered under the substantial equivalence route. An application for a full safety evaluation would have to be made under the Novel Foods Regulation. However, this was simply a procedural matter as the ACNFP had already conducted a full safety evaluation under the voluntary scheme and would forward its advice to the Commission when a full application was received.

3.2 INSECT-PROTECTED GM COTTONSEED

The Committee received a submission from Monsanto Europe SA seeking an opinion on the substantial equivalence of oil and linters derived from GM cottonseed. The cotton line 531 has been genetically modified to produce the CRYIA(c) protein which has insecticidal activity to specific lepidopteran pests. The genetic modification involved the insertion of three genes; the *cryIA(c)* gene, a neomycin phosphotransferase II (*nptII*) gene and a 3^{''}(9)-O-aminoglycoside

adenylyltransferase (*aad*) gene. The *aad* gene is not expressed in the plant. The submission stated that both the oil and the linters are extensively processed and therefore no intact proteins or genetic material are expected to be present in food products derived from the cotton.

The ACNFP requested further data to demonstrate the absence of DNA and protein in processed cottonseed oil. The Committee also asked for further compositional data on the oil. Cotton linters are processed to produce the food additives carboxy methylcellulose (E466) and methylcellulose (E461) which are not controlled by the Novel Foods Regulation, but by EC food additives legislation.

In the absence of the additional data requested, the Committee was unable to reach an opinion on substantial equivalence of the cottonseed oil at this stage.

3.3 HERBICIDE TOLERANT GM COTTONSEED

The ACNFP also received a submission from Monsanto Europe SA seeking an opinion on the substantial equivalence of oil and linters derived from herbicide tolerant GM cotton. The cotton has been modified to produce a protein, CP4 enolpyruvylshikimate-3-phosphate synthase (EPSPS), which confers tolerance to the herbicide glyphosate. The cotton also contains an *nptII* gene and an *aad* gene. As with the previous cotton line the *aad* gene is not expressed in the plant.

The Committee requested further data before it could give an opinion on substantial equivalence.

3.4 INSECT-PROTECTED GM POTATO

Monsanto also submitted an application seeking an opinion on the substantial equivalence of food and food ingredients derived from potatoes that had been genetically modified for insect-resistance. Five potato lines had been modified to produce the CRYIIIA protein which confers resistance to the Colorado Beetle (*Leptinotarsa decemlineata*). Four of the potato lines also contained a *nptII* gene (one of these lines also contained an *aad* gene), the fifth contained only the *cryIIIA* gene. The potatoes will be used for potato chip and potato crisp production. They are also used to produce dehydrated potato products such as flakes, granules or starch.

The ACNFP considered that the potato products were not highly refined and would contain intact or degraded DNA and denatured proteins and thus, it would not be appropriate to apply the concept of substantial equivalence. The Committee asked for further data to enable a full safety assessment of the GM potato lines to be carried out.

3.5 INSECT-PROTECTED GM MAIZE

The ACNFP considered a submission seeking a view on the substantial equivalence of food ingredients derived from GM maize line (MON 802) and its progeny. The maize had also been developed by Monsanto and had been genetically modified to be resistant to insect pests such as the European corn borer. The maize also contained two genes encoding for tolerance to the herbicide glyphosate, as well as an *nptII* antibiotic resistance gene.

As with the GM potato the ACNFP advised that it was not appropriate to apply the concept of substantial equivalence to the GM maize. Instead a full safety evaluation should be carried out. The Committee asked for further agronomic data on the GM crop and GM crop sprayed with the herbicide. Further data were also requested on the presence of novel DNA and proteins in processed food products derived from the maize, along with some additional information on the *nptII* gene and its stability.

4. OTHER ACTIVITIES

4.1 IMPROVING THE TRANSPARENCY OF THE ACNFP

In December 1997, the ACNFP considered the issue of how further to improve the transparency of its work. For a number of years the ACNFP has published its agendas in advance of meetings, published a note of the proceedings immediately after a meeting and has published its advice on submissions once an evaluation had been completed. The ACNFP now wished to consider what further steps might be taken to improve openness. Accordingly, the Committee discussed the possibility of holding open meetings, of publishing the minutes of its meetings and producing a regular newsletter. The Committee agreed to publish the minutes of meetings and make copies of committee papers publicly available wherever possible. Commercially sensitive material would however continue to be withheld. The Committee agreed to the principle of holding open meetings wherever possible, particularly on key generic topics.

4.2 CRITICAL ISSUES FOR THE SAFETY ASSESSMENT OF NOVEL FOODS WHEN NO CONVENTIONAL COUNTERPART EXISTS: A JOINT MEETING WITH THE COMMITTEE ON TOXICITY (COT)

In recent years the Committee has gained much experience in looking at submissions on novel foods for which there is no existing counterpart. Examples of these types of novel foods include fat replacers, fibres and proteins produced by bacterial fermentation. When considering submissions such as these, the ACNFP routinely sought the advice of the COT on the toxicology data and, where available, the human clinical data submitted. Both Committees identified a number of key areas where the approaches currently used in safety assessment could not readily be applied to the area of novel foods, for example the role of animal studies in comparison with human studies. Important scientific issues such as how to assess the potential allergenicity of novel foods and the possible need for some form of post-market surveillance of newly approved novel foods were also identified. The ACNFP agreed to hold a joint meeting with the COT to discuss these and other issues. The meeting took place in early 1998. Further details of the meeting will be available in the 1998 ACNFP Annual Report and it is intended to publish the outcome of the meeting in the scientific press.

4.3 CONSIDERATION OF THE DIETARY IMPLICATIONS OF CUMULATIVE NUTRITIONAL CHANGES IN INDIVIDUAL NOVEL FOODS AND EXISTING FOODS

The Committee discussed the general issue of the dietary implications of cumulative nutritional changes in individual novel foods and conventional foods. The issue arose out of the Committee's consideration of the novel oil derived from a new variety of linseed (see section 2.4). The ACNFP was concerned that the oil had been altered using traditional plant breeding techniques to contain lower levels of the nutritionally beneficial fatty acid α -linolenic acid, in order to improve the shelf-life of the oil. The ACNFP considered that such a change carried out to meet

technical and commercial needs may have an adverse nutritional outcome and recognized that this problem was not unique: a number of vegetable oils had been gradually altered through the use of traditional plant breeding techniques, such that the nutritional profile of the oils had changed considerably. The ACNFP considered that such important nutritional issues should be referred to COMA for advice. COMA considered the issue at its meeting in October and it was agreed that a small working group consisting of selected COMA and ACNFP members and other interested parties should be set up to consider this issue.

5. DEVELOPMENTS ELSEWHERE

5.1 EUROPEAN COMMISSION PROPOSAL FOR A DIRECTIVE ON FOOD IRRADIATION

In December 1988, the EC published a proposal for a Council Directive (COM(88)654) concerning foods and food ingredients treated with ionising radiation¹⁴. Despite early agreement on the technical controls, it had not been possible to reach agreement on the range of foods to be approved for treatment. However, on the 27 October 1997 a Common Position on this matter was formally adopted at the Internal Market Council (IMC). The text was passed back to the European Parliament for its second reading, which took place on 18 February 1998 where a number of amendments were adopted. These amendments will now be considered further by the Commission and the Member States.

Details of the current position can be obtained from the MAFF Secretary (see page 17).

5.2 LABELLING OF GM FOODS

The European Commission announced on 25 July 1997 an orientation paper outlining its intention to introduce a more coherent, mandatory labelling policy for GM food products. The European Commission has also adopted a Regulation which came into force on 1 November 1997¹⁵ which applies the same general labelling rules as those in the Novel Foods Regulation to GM soya and maize, (which were approved for food use prior to the Novel Foods Regulation coming into force). The European Commission is currently seeking urgent agreement on more detailed rules based on the detection of protein or DNA arising from the modification. These detailed rules were agreed by Member States on 20 May 1998 and will come into force on 1 September 1998¹⁶.

Meanwhile, in the UK, retailers and manufacturers announced in November 1997 that they would introduce voluntary labelling of foods containing GM soya and maize protein from the 1997 harvest with effect from January 1998.

Details of the current position can be obtained from the MAFF Secretary (see page 17).

6. CONTACT POINTS

For further information about the general work of the Committee or about specific scientific points concerning individual submissions (which have been made or are being made) contact in the first instance:

The MAFF Secretary,
Mr Nick Tomlinson,
Ministry of Agriculture, Fisheries and Food,
Room 235, Ergon House,
c/o Nobel House
17 Smith Square
London SW1P 3JR

email: n.tomlinson@csf.maff.gov.uk

Information about health or toxicological matters may be obtained by contacting, in the first instance:

The DH Secretary,
Mrs Sue Hattersley
Department of Health,
Room 653C, Skipton House,
80 London Road,
London SE1 6LW.

email: s.hattersley@hefm.demon.co.uk

Information on the ACNFP is also available on the MAFF website (<http://www.maff.gov.uk>) in the food pages.

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).
3. Advisory Committee on Novel Foods and Processes. *Annual Report 1991*. Department of Health and Ministry of Agriculture, Fisheries and Food, 1992. (Available from the ACNFP Secretariat).
4. Advisory Committee on Novel Foods and Processes. *Annual Report 1992*. Department of Health and Ministry of Agriculture, Fisheries and Food, 1993. (Available from the ACNFP Secretariat).
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).
6. Advisory Committee on Novel Foods and Processes. *Annual Report 1994*. Department of Health and Ministry of Agriculture, Fisheries and Food, 1995. (Available from the ACNFP Secretariat).
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8. Advisory Committee on Novel Foods and Processes. *Annual Report 1996*. Department of Health and Ministry of Agriculture, Fisheries and Food 1997 (Available from the ACNFP Secretariat).
9. European Commission. Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients. Official Journal of the European Communities, No L43 of 14th February 1997.
10. SI 1997 No.1335. The Novel Foods and Novel Food Ingredients Regulations 1997.
11. SI 1997 No.1336. The Novel Foods and Novel Food Ingredients (Fees) Regulations 1997.
12. Scientific Committee for Food, 1997. Opinions on the assessment of novel foods. Official Journal of the European Communities No L253 of 16th September 1997.
13. Committees on Toxicity, Mutagenicity and Carcinogenicity of Chemicals in Food, Consumer Products and the Environment. *Annual Report 1997*. HMSO 1998.

14. 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.
15. European Commission. Regulation (EC) No 1813/97 of the European Parliament and of the Council concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC. Official Journal of the European Communities, No L257 of 20th September 1997.
16. European Commission. Regulation (EC) No 1139/98 of the European Parliament and of the Council concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC. Official Journal of the European Communities, No L159 of 3rd June 1998.

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 7BO.

8. GLOSSARY

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

antioxidant: a compound which helps prevent oxidation of molecules such as fats and lipids.

DNA: deoxyribonucleic acid (DNA) which is found in living cells and contains the information for cellular structure, organisation and function.

ELISA: enzyme-linked immunosorbent assay.

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.

fatty acids: carboxylic acids found in fats and oils. They consist of a chain of up to thirty carbon atoms with attached hydrogen atoms and a terminal acid group.

flavonoids: compounds in which two 6-carbon rings are linked by a 3-carbon unit. These compounds are found in fruit and vegetables and have a range of biological activities.

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.

genetically modified organism: an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

genome: a complete ensemble of the genes in a cell e.g. chromosomal and plasmid elements.

glycoalkaloids: a diverse group of nitrogen-containing substances that are produced by plants and have potent effects on body functions.

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

hybrid: seed produced from a cross between genetically dissimilar parents.

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

labile: liable to displacement or change

lepidopteran: belonging to the insect order Lepidoptera, including butterflies and moths, which have scaled wings.

linters: short fibres from around the seed of the cotton plant.

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

polyunsaturated fatty acid: fatty acids containing more than 1 unsaturated linkage (double bond).

progeny: offspring.

pro-oxidant: a compound which promotes oxidation

triglyceride (triacylglycerol): the major component of fats and oils. They consist of a glycerol backbone with three attached fatty acids. The three fatty acids can be identical, two the same or all different.

APPENDIX I

ACNFP: REMIT, MEMBERSHIP AND LIST OF MEMBERS' INTERESTS,
CODE OF CONDUCT AND INTERACTIONS WITH OTHER COMMITTEES

Remit

The Advisory Committee on Novel Foods and Processes 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”.

The Secretariat is provided jointly by officials of the Department of Health and the Ministry of Agriculture, Fisheries and Food. As well as formal meetings, the Committee organises workshops on specific topics related to its remit.

The interaction between the ACNFP and other independent advisory committees is outlined in Figures 1 and 2.

Membership and Members' Interests

The membership of the Committee provides a wide range of expertise in fields of relevance in the assessment of novel foods and processes. A list of the membership during 1997, together with the names of assessors and the secretariat may be found overleaf.

In common with other independent advisory committees the ACNFP is publishing a list of its members' commercial interests. These have been divided into different categories relating to the type of interest:-

Personal: a) direct employment or consultancy;
 b) occasional commissions;
 c) shareholdings.

Non-personal: a) fellowships;
 b) support which does not benefit the member directly e.g. studentships.

Details of the interests held by members during 1997 can be found on pages 26–28.

A copy of the code of conduct for ACNFP members can be found on pages 29–33.

MEMBERSHIP OF THE COMMITTEE DURING 1997

Chairman

Professor Derek C Burke, CBE, BSc, PhD, HonLLD, HonScD, DL
Former Vice-Chancellor, University of East Anglia (until August 1997)

Professor Janet Bainbridge, BSc, PhD, GradCertEd(Tech), SOFHT, FRSA
School of Science and Technology, University of Teesside, Middlesbrough
(from September 1997)

Members

Professor P J Aggett², MSc, MB, ChB, FRCP (Lond, Edin & Glasg), DCH
Assistant Director, Institute of Food Research, Norwich

Professor A Atkinson, BSc, PhD
Former Deputy Director of PHLS Centre for Applied Microbiology and
Research, Porton Down, Wiltshire (until August 1997)

Professor C M Brown, BSc, PhD, DSc, CBiol, FIBiol, FIBrew, FRSE
Vice Principal, Heriot-Watt University, Edinburgh (from September 1997)

Dr M J Gasson, BSc, PhD
Head of Department of Genetics and Microbiology,
Institute of Food Research, Norwich

Dr J Heritage, BA, DPhil, CBiol, MIBiol
Department of Microbiology
University of Leeds (from September 1997)

Professor W P T James, CBE, MA, MD, DSc, FRCP, FRCP (Edin), FRSE
Director, Rowett Research Institute, Aberdeen

Professor D A Ledward, MSc, PhD, FIFST
Professor of Food Science, University of Reading

Professor B J Miflin, BSc, MS, PhD
Director, Institute of Arable Crops Research,
Rothamsted Experimental Station

Mrs H Millar, MA, FRSA
Formerly of the Adult Education Department,
University of Glasgow

Professor B E B Moseley, OBE, BSc, PhD
Retired Head of the Institute of Food Research,
Reading Laboratory

²Now at Lancashire Postgraduate School of Medicine and Health, University of Central Lancashire,
Preston.

Reverend J C Polkinghorne, KBE, MA, PhD, ScD, FRS
Former President of Queens' College, Cambridge

Dr P J Rodgers, MA, DPhil
Formerly of Zeneca BioProducts,
Billingham, Cleveland (until August 1997)

Professor I Rowland, BSc, PhD (from September 1997)
Director, Northern Ireland Centre for Diet and Health
University of Ulster, Coleraine.

Professor T Sanders, BSc, PhD, DSc
Head of Department of Nutrition and Dietetics,
Kings College, London.

Dr N A Simmons FRC Path, FIFST
Emeritus Consultant in Microbiology to the
Guy's & St Thomas' Hospital Trust, London;
Honorary Senior Lecturer in Microbiology, St Bartholomew's
and the Royal London School of Medicine and Dentistry.

Professor J E Smith, BSc, MSc, PhD, DSc, FIBiol, FRSE
Head of the Applied Microbiology Division, Department of
Bioscience and Biotechnology, University of Strathclyde (until August 1997)

Professor R Walker PhD, CChem, FRSC, FIFST
Professor of Food Science, University of Surrey

Professor H F Woods BSc, BM BCh, DPhil,
Hon.FFOM, FIFST, FFPM, FRCP (Lond & Edin)
Dean of the Faculty of Medicine, University of Sheffield

Assessors

Dr P Baker	Department of Trade and Industry (until May 1997)
Dr I Lawrence	Department of Trade and Industry (from May 1997)
Dr J Bell	Ministry of Agriculture, Fisheries and Food
Mr S McLean	Health and Safety Executive
Dr F Amijee	Department of the Environment
Professor A Gilmour	Department of Agriculture, Northern Ireland
Mr I Jackson	Welsh Office
Ms M McAllen	Scottish Office, Agriculture and Fisheries Department

Personal Interest		Non-Personal Interest		
Member	Company	Interest	Company	Interest
Prof P J Aggett	Nestec, Wyeth	Ad hoc consultancy	Nestec, Milupa, Nutricia, Wyeth, Ajinomoto FDF Unilever	Departmental commissioned research and consultancies
Prof T Atkinson	None		None	
Prof J Bainbridge	None	None	Various	Departmental commissioned research and student placements
Prof C M Brown	None		None	
Prof D C Burke	None		None	
Dr M J Gasson	None		Various	Departmental commissioned research
Dr J Heritage	None		None	
Prof W P T James	None		Palm Oil Inst. of Malaysia.	Supporting work on the Food Standards Agency
Prof D A Ledward	None		Various	Departmental teaching & research funded by various food companies
Prof B J Mifflin	MicroBio Limited	Non-executive Director		
	CIBA Seeds (Novartis)	Ex-employee, occasional contact maintained, shareholder		

Personal Interest		Non-Personal Interest		
Member	Company	Interest	Company	Interest
Mrs H Millar	Unilever	Shareholder	None	
Prof B E B Moseley	None		None	
Rev J Polkinghorne	None		None	
Dr P J Rodgers	Zeneca Ltd Marlow Foods Ltd F. Hoffmann-La Roche Ltd	Shareholder, former employee Consultancy Consultancy	None	
Prof I Rowland	Yakult	Consultancy (lapsed)	Coca-Cola, Unilever, Biscuit, Cocoa, Chocolate, Confectionery Alliance Medici Pharmaceuticals Kelloggs Kirin Scotia Lipidtechnik/ Scotia pharmaceuticals	Research Research Research Research Research Research Research
Prof T Sanders	Nutrasweet Seven Seas Ltd Coca-cola ILSI Europe	Consultancy Consultancy (lapsed) Consultancy Consultancy	Unilever Cultor Food Science	Free supply of oils & fats for research purposes Research grant
Dr N A Simmons	Food Micro Ltd Infection Management Ltd Marks & Spencer plc McDonalds Restaurants Ltd PPP/Columbia Healthcare Ltd Waitrose Ltd Worshipful Company of Fishmongers	Director and Shareholder Advisor and Shareholder Consultant and Advisor Consultant and Advisor Consultant Consultant and Advisor Bacteriologist	None	

	Personal Interest		Non-Personal Interest	
Member	Company	Interest	Company	Interest
Prof J E Smith	Nestlé (Switzerland), Rhône Poulénc Diagnostics	Consultancy Royalty Agreement	Robertson Trust, Cow & Gate, Rhône Poulénc Diagnostics	Staff Support Research Research
	Cadbury Beverages, Proctor & Gamble, IDV Ltd, Food Safety Advisory Centre, Coffee News Information Service, RHM, Tate & Lyle	Consultancy Consultancy Consultancy Consultancy Consultancy Consultancy (lapsed) Consultancy (lapsed)	Nestle Ltd	Research
Prof H F Woods	None	None	Wide range of national and international food and chemical companies	Dean of the University of Sheffield Faculty of Medicine which has extensive activity in teaching and research in nutrition and toxicology and in topics related to and supported by, many companies in the food and chemical industry. Trustee of the Harry Bottom Charitable Trust and Special Trustees for the former United Sheffield Hospitals.

REGISTER OF INTERESTS: A CODE OF CONDUCT FOR MEMBERS OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Introduction

1. This code of conduct guides members of the Advisory Committee on Novel Foods and Processes as to the circumstances in which they should declare an interest in the food industry.
2. The advice of the Advisory Committee concerns matters which are connected with the food industry and it is therefore desirable that its members and those of its support groups should have a good understanding of the work of the industry. It is also desirable that some members should have practical experience of the scientific problems of product development and safety evaluation. The food industry relies heavily on the advice of a wide range of specialists including scientists outside the industry in, for example, the universities. To avoid any public concern that commercial interests might affect the advice of the Committee, Ministers have decided that the arrangements which govern relationships between members and the food industry and information on significant and relevant interests should be on public record.

Definitions

3. In this code, 'food industry' means:
 - (i) companies, partnerships or individuals who are involved with the production, manufacture, packaging, sale or supply of food or food processes, subject to the Food Safety Act 1990;
 - (ii) trade associations representing companies involved with some products;
 - (iii) companies, partnerships or individuals who are directly concerned with research, development or marketing of a food product which is being considered by the ACNFP.
4. In this code 'the Secretariat' means the Secretariat of the ACNFP.

Different types of interest

5. The following is intended as a guide to the kinds of interests which should be declared. Where a member is uncertain as to whether an interest should be declared he should seek guidance from the Committee's Secretariat or, where it may concern a particular product which is to be considered at a meeting, from the Chairman at that meeting. **If a member has an interest not specified in these notes but which he believes could be regarded as influencing his advice, he should declare it.** However, neither the members nor the Secretariat are under an obligation to search out links between one company and another, for example where a company with which the member is connected has an interest in a food industry company of which the member is not aware and could not reasonably be expected to be aware.

Personal Interests

6. A personal interest involves payment to the member personally. The main examples are:-

- (i) Consultancies: any consultancy, directorship, position in or work for the food industry which attracts regular or occasional payments in cash or kind.
- (ii) Fee-Paid Work: any work commissioned by the food industry for which the member is paid in cash or kind.
- (iii) Share holdings: any share holding in or other beneficial interest in shares of the food industry. This does not include share holdings through unit trusts or similar arrangements where the member has no influence on financial management.

Non-Personal Interests

7. A non-personal interest involves payment which benefits an organisation or department for which a member is responsible, but is not received by the member personally. The main examples are:-

- (i) Fellowships: the holding of a fellowship endowed by the food industry.
- (ii) Support by the Food Industry: any payment, other support or sponsorship by the food industry which does not convey any pecuniary or material benefit to a member personally but which does benefit his position or department, eg
 - a. a grant from a company for the running of a unit or department for which a member is responsible;
 - b. a grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which a member is responsible. This does not include financial assistance for students;
 - c. the commissioning of research or other work by, or advice from, staff who work in a unit for which a member is responsible.

Members are under no obligation to seek out knowledge of work done for or on behalf of the food industry by departments for which they are responsible, if they would not normally expect to be informed. Where members are responsible for organisations which receive funds from a very large number of companies involved in the food industry, the Secretariat can agree with them a summary of non-personal interests rather than draw up a long list of companies.

- (iii) Trusteeships: any investment in the food industry held by a charity for which an ACNFP member is a trustee.

Where a member is a trustee of a charity with investments in the food industry, the Secretariat can agree with the member a general declaration to cover this interest rather than draw up a detailed portfolio.

Contractual obligations of confidentiality

8. Some members of the Committee may, **at the time of adoption of this Code** or (in the case of new members) on their joining the Committee, be bound by the terms of a contract which requires them to keep the fact of the contractual arrangement confidential. As a transitional measure any member so affected shall seek to agree an entry for the public register with the other party. If such agreement does not prove possible, the member shall seek a waiver permitting him to disclose his interest, in confidence, to the Chairman and the Secretariat. The Secretariat will maintain a confidential register of such disclosures which will not form part of the public record.

9. On adoption of this Code members shall not enter into new contractual obligations which would inhibit their ability to declare a relevant interest.

Declaration of interests to the Secretariat

10. Members of the Committee, should inform the Secretariat **in writing** when they are appointed of their **current personal and non-personal** interests, including the principal position held. Only the name of the company and the nature of the interest is required, the amount of any salary, fees, shareholding etc need not be disclosed to the Secretariat. An interest is current if the member has an on-going financial involvement with the food industry eg if he holds shares in a food company, if he is in the consultancy contract with the food industry, or if he is in the process of carrying out work for the food industry. Members are asked to inform the Secretariat at the time of any change of their **personal** interest, and will be invited to complete a declaration form once a year. It would be sufficient if changes in non-personal interests are reported in the annual declaration form following the change. (Non-personal interests involving less than £1000 from a particular company in the previous year need not be declared to the Secretariat.)

Special position of Chairman

11. It is not appropriate for the Chairman of the Advisory Committee on Novel Foods and Processes to have any current personal interest in the food industry.

Declaration of interests at meetings and participation by members

12. Members are required to declare relevant interests at Committee meetings, and to state whether they are personal or non-personal interests and whether they are specific to the product under consideration or non-specific:

- (i) A member must declare a **personal specific** interest if he has at any time worked on the product or process under consideration and has personally received payment for that work, in any form, from the food industry. The member shall take no part in the proceedings as they relate to the product and will be required to leave the Committee during the discussions. If the interest is no longer current, the member should declare it as a **lapsed personal specific** interest;

- (ii) A member must declare a **personal non-specific** interest if he has a current personal interest in the food company concerned which does not relate specifically to the product under discussion. The member shall take no part in the proceedings as they relate to the product, except that he may at the Chairman's discretion answer questions from other members;
- (iii) A member must declare a **non-personal specific interest** if he is aware that the department for which he is responsible has at any time worked on the product or process but the member has not personally received payment in any form from the food industry for the work done. The member may take part in the proceedings unless he has personal knowledge of the product or process through his own work or through direct supervision of other people's work, in which case he should declare this and not take part in the proceedings (except to answer questions);
- (iv) There is no need for members to declare **non-personal non-specific** interests (ie if a member is aware that the department for which he is responsible is currently receiving payment from the food industry company concerned which does not relate specifically to the product or process under discussion). If, exceptionally, a member feels such an interest might be thought to influence his advice, he should seek guidance from the Chairman on whether to draw the facts to the attention of other members.

13. The examples, of 'personal', 'non-personal' and 'current' interests given in the previous paragraphs should be read in the context of paragraphs 6, 7 and 10. 'Taking part in the proceedings' includes both speaking and, if necessary, voting. A member who is in any doubt as to whether he has an interest which should be declared, or whether he should take part in the proceedings, should ask the Chairman for guidance. The Chairman has the power to determine whether or not a member with an interest shall take part in the proceedings.

14. If a member is aware that a product or process under consideration is or may become a competitor of a product or process manufactured, sold or supplied by a company in which the member has a **current personal** interest, he should declare his interest in the company marketing the rival product or process. The member should seek the Chairman's guidance on whether he should take part in the proceedings.

Register of interests

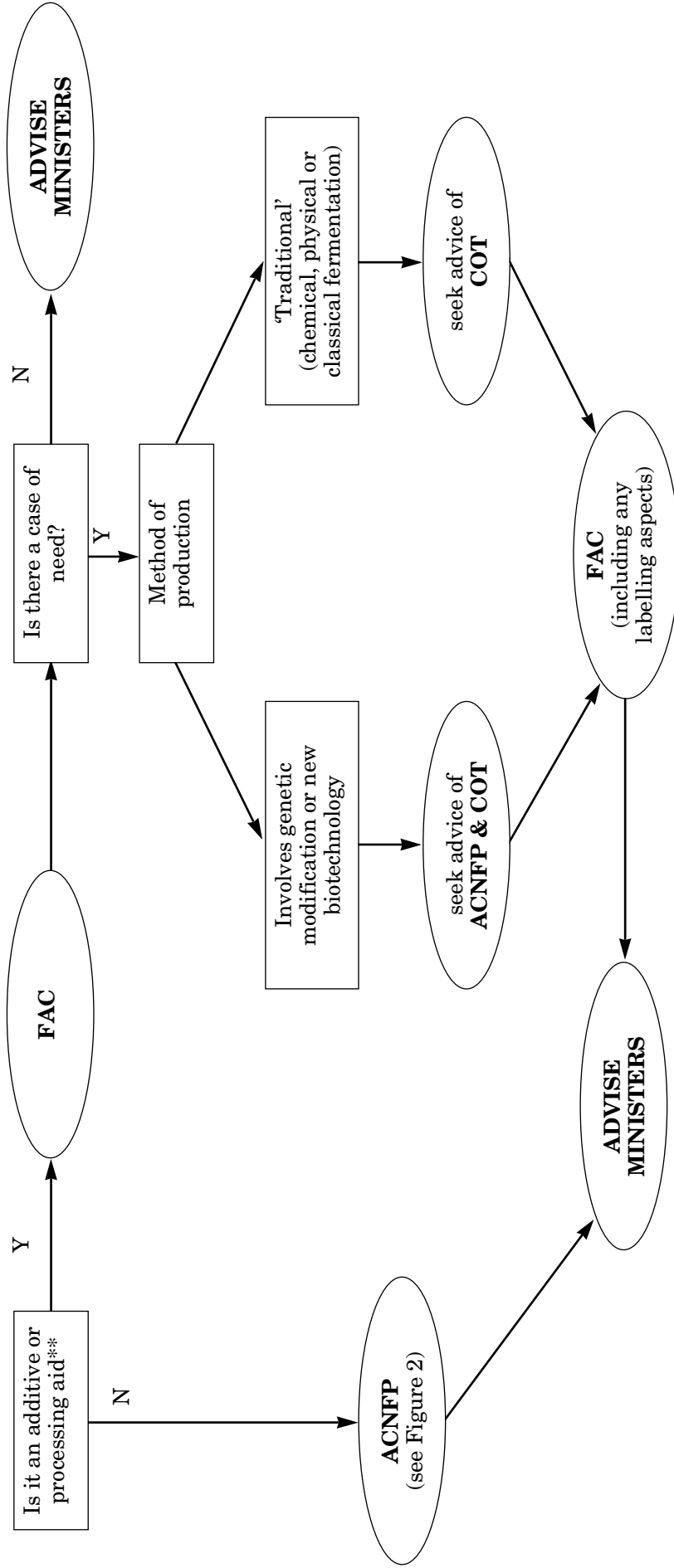
- 15.** A record is kept by the Secretariat of:
- (i) names of members who have declared interests to the Secretariat on appointment, when an interest first arises or through the annual declaration, and the nature of the interest;
 - (ii) names of members who have declared interests at meetings of the Committee, giving dates, names of relevant products and companies, details of the interest declared and whether the member took part in the proceedings.

Publication

- 16.** Information about interests declared by members to the Secretariat will be published each year in the Annual Report of the ACNFP.

Figure 1: Decision Tree for allocation of Submissions to ACNFP or FAC.

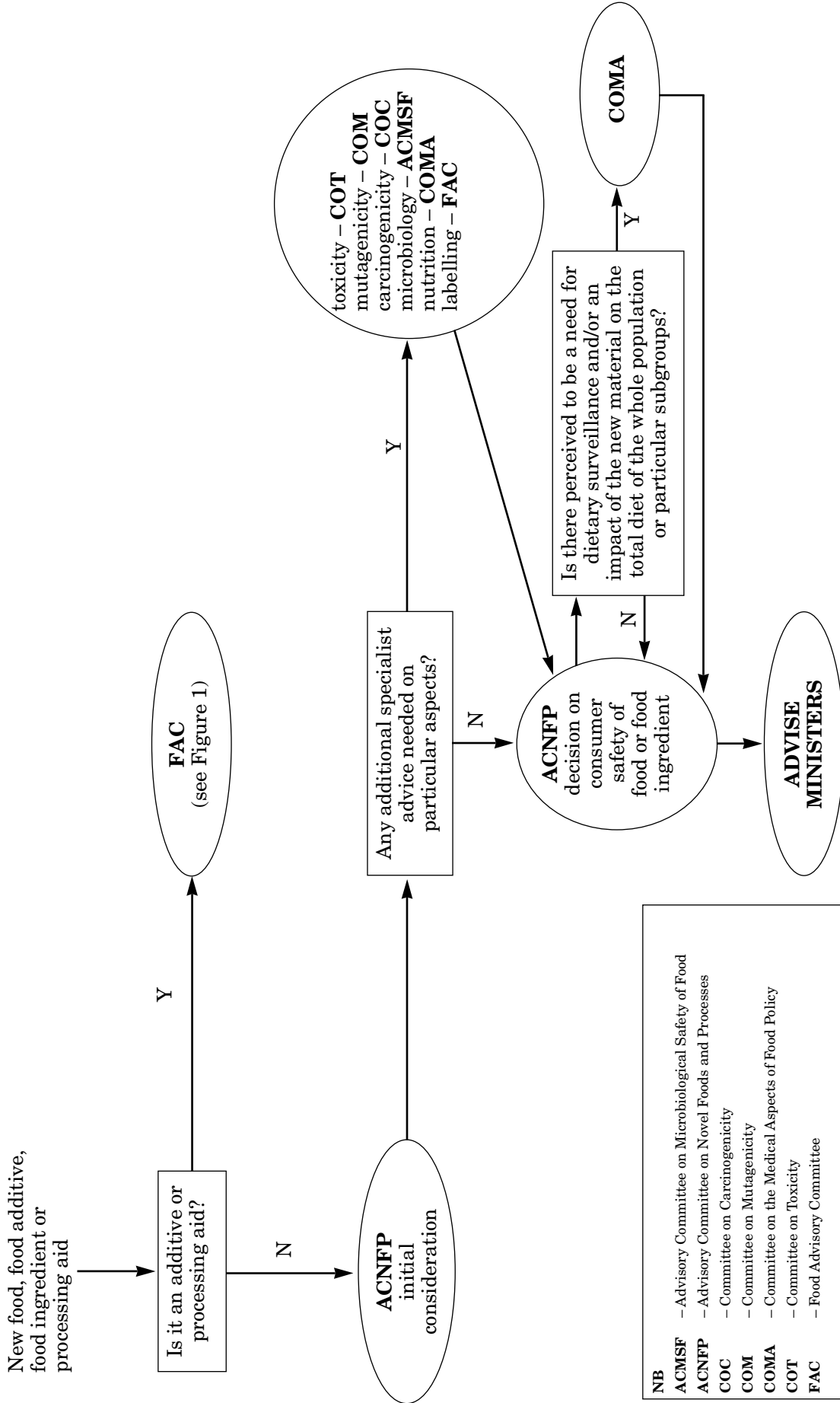
New food, food additive,
food ingredient or
processing aid*



* If a medicinal licence has been applied for, or any medical claims are made for the product, then the Medicines Control Agency will need to be consulted.

** Using definitions from Council Directive 89/107/EEC of 21/12/88 – Food Additives Authorised for Use in Foodstuffs Intended for Human Consumption.
Use of this decision tree will involve consideration of the extent of use (with implications for dietary intake), whether other uses are likely to result in a changed classification giving a different route of evaluation and the status of the substance with respect to existing additive regulations.

Figure 2: Relationship of ACNFP with other Expert Committees involved in the assessment of food safety.



- NB**
- ACMSF** – Advisory Committee on Microbiological Safety of Food
 - ACNFP** – Advisory Committee on Novel Foods and Processes
 - COC** – Committee on Carcinogenicity
 - COM** – Committee on Mutagenicity
 - COMA** – Committee on the Medical Aspects of Food Policy
 - COT** – Committee on Toxicity
 - FAC** – Food Advisory Committee

APPENDIX II

ACNFP REPORT ON PEELED AND COMMINUTED TOMATO PRODUCTS
FROM GENETICALLY MODIFIED TOMATOES:
SUPPLEMENTARY SUBMISSION TO FEBRUARY 1996 CLEARANCE

INTRODUCTION

1. In February 1997 the Committee considered a further supplementary submission¹ from Zeneca Plant Science (the Company) requesting food safety evaluation for peeled and comminuted processed tomato products produced from hybrid lines derived from the genetically modified (GM) inbred line TGT7-F.

2. The original submission² received in August 1994 requested food safety clearance of tomato paste from genetically modified (GM) cultivated tomato, *Lycopersicon esculentum* Mill. (family: Solanaceae). Tomatoes had been genetically modified to improve fruit quality by the reduction of the pectin-degrading enzyme, polygalacturonase (PG). Ministers accepted the ACNFP's advice and, in February 1995, the Committee published its Report³ detailing clearance of the food use of paste from two GM hybrid lines derived from the GM inbred line TGT7-F.

3. A supplementary submission⁴ was received in August 1995 requesting that the scope of the original clearance be extended to tomato paste and processed tomato products containing the paste (ketchup, pizza sauces) from three additional GM lines. The Company also sought a much broader food safety clearance of tomato paste (and its products) from:

- (a) any tomato hybrid line derived from the GM inbred line TGT7-F; and,
- (b) any tomato lines genetically modified with construct pJR16S.

4. In February 1996, Ministers again accepted the ACNFP's advice and announced their decision to extend the clearance of food use of paste and products containing the paste, from any tomato hybrid line derived from the GM inbred line TGT7-F and the Committee Report⁵ was published. However, the Committee was not in a position to be able to recommend that general clearance be given to any inbred or hybrid lines containing the construct pJR16S obtained from a different transformation event.

5. As in its evaluation of the original submission from the Company, the Committee focused upon the consumer food safety aspects of the peeled and comminuted processed tomato products from the hybrid lines derived from the GM inbred line TGT7-F. As hybrids derived from the GM inbred line TGT7-F have been reviewed and cleared by the Committee, no further evidence was submitted by the company pertaining to the genetic modification or the genetic stability of the introduced genes. The Committee considered the nutritional and toxicological evidence presented by the Company to compare the products produced with their non-GM counterparts.

BACKGROUND

6. The reduction of PG activity by genetic modification of the tomatoes, enables the fruit to ripen normally but soften less quickly. This improves fruit quality in terms of higher soluble solids content and increased viscosity, which are the desired processing characteristics for tomato paste manufacture. The new varieties, which can be vine-ripened for longer than existing conventionally-bred varieties before harvest, are better able to survive handling and transport and less likely to break down during processing. Further information on the rationale for the genetic modification is given in the Committee's first Report³.

PROCESS DESCRIPTION AND USE

7. The GM tomatoes will have the same processing regime for the comminuted tomato products as described previously for tomato paste^{3&2}. Essentially, this involves an initial “hot breaking” step during which the chopped tomatoes will be heat treated at temperatures greater than 93°C followed by tomato material extraction, sieving, pulp concentration by boiling and a final, “hot-filled” canning sterilisation step. Products derived from the tomato paste will be processed further and repackaged for final heat sterilisation. Quantitative data on processing performance of the new GM lines confirmed that the GM fruit displayed improved processing characteristics (the intended effect of genetic modification) over non-GM controls.

8. The peeled tomato products require the removal of the skin. The three main commercial types of skin removal involve the use of steam/blanching, caustic soda or infra-red radiation. Temperatures of 90°C-100°C for a maximum of 60 seconds are used for steam and caustic soda peeling whereas infra-red peeling involves temperatures in excess of 700°C for up to 20 seconds.

9. As the caustic peeling method is prohibited for processing tomatoes in Europe, newer methods such as wet steam peeling and dry vacuum systems are being developed.

10. After the peeling process, tomatoes to be sold as whole peeled tomato fruit will be sorted by size and packed into containers. Tomatoes to be sold as a diced/chopped product are peeled, cut as appropriate and packed into containers. Tomato juice or puree is then added to the top of the container along with other ingredients if necessary before closure of containers and sterilisation by heat.

PRODUCT SPECIFICATION

11. As in the previous submissions, the tomato products will be produced in accordance with existing food legislation and will comply with Codex Standard (57-1981).

SAFETY ASSESSMENT

12. The Committee has previously established the food safety of the GM tomato from TGT7-F hybrids for both fresh fruit and commercially available comminuted products such as paste. However, the Committee considered comparative analytical data from the GM peeled products in comparison with non-GM controls to assess the safety of other tomato products derived from the GM TGT7-F hybrids. These data demonstrated that the GM tomato products were comparable to the non-GM counterparts.

13. In particular, the Committee considered the nutritional composition of the peeled products, the presence of naturally occurring toxins, the viability of the seeds after processing and the degradation of the aminoglycoside-3'-phosphotransferase (APH (3') II) protein produced by the *nptII* (*kan^r*) marker gene.

14 Comparative nutritional analyses were carried out on the diced and chopped GM tomatoes packed in tomato juice produced during the 1995 Italian trials. These were grown under the same conditions at the same site and were harvested and processed in the same way as the non-GM control fruits. Two commercially available products were also analysed. The Committee was satisfied that the nutritional values of the GM tomato products fell within the range of the controls. This demonstrated that the genetic modification did not change the nutritional profile of the peeled product.

15. The tomato, in common with other members of the family Solanaceae, is known to have the potential to accumulate naturally occurring toxins known as glycoalkaloids. The main toxin that could be present in fresh tomatoes is α -tomatine, and the method of its determination and its localisation throughout the plant was detailed in the original submission. Further analytical data was presented by the Company on 4 toxins known to occur in tomatoes (α -tomatine, solanine, chaconine and nicotine). The Committee was satisfied that the levels of these naturally occurring toxins were below the level of detection in both the modified and the unmodified control samples.

16. In the original submission it was shown that the APH (3') II protein was degraded during the manufacture of the tomato paste. The production of the peeled product involves a less vigorous heating regime to that of the paste. As it was demonstrated in the original submission that the protein is present in the fresh tomato, the latest data from sensitive ELISA* assays showed that the APH (3') II protein was below the level of detection in the peeled GM tomato product. The Committee was satisfied that the peeling and sterilisation process of the peeled product is sufficient to degrade the APH (3') II protein.

17. The manufacture of peeled and some comminuted products will result in the final product containing seed. The Committee was satisfied that germination studies on seed taken from GM peeled, processed products manufactured in Italy in 1995, alongside seed taken from unprocessed modified and unmodified tomato fruits demonstrated that under standard germination conditions the seeds from the processed product were incapable of germination.

*Technical terms not explained in the body of the report are underlined where they appear for the first time and are explained in the glossary on page 20; explanations are used in the context of the report and should not be taken as general definitions.

DISCUSSION

18. The Committee has previously established the food safety of the GM tomato from TGT7-F hybrids for both fresh fruit and commercially available comminuted products such as paste. Therefore, the Committee focused its assessment on the characteristics of the peeled tomato product. The safety assessment centred on the establishment of nutritional equivalence, absence of naturally occurring toxicants, destruction of the *nptII* gene product by the manufacturing process and non-viability of the seeds that remained in the final products.

19. The Committee was satisfied that the composition of the peeled products from the GM tomatoes was comparable – nutritionally and toxicologically – to products produced from conventionally-bred tomatoes currently consumed as part of the UK diet.

20. The gene product of the introduced *nptII* gene, the APH (3') II enzyme, is a heat labile protein. The new processed products will be subjected to a temperature and processing regime similar to that described in the original submission. This has been shown to destroy the introduced protein. The processing of the peeled and chopped product is less vigorous than that used in paste production. ELISA analyses of the peeled product demonstrated that the APH (3') II protein was below the level of detection after the manufacturing process. These results satisfied the Committee that the manufacturing process degraded the introduced *nptII* gene product.

21. The peeled and chopped products would also contain seeds, therefore germination studies were carried out. The Committee was satisfied that the results of these studies showed that the manufacturing process rendered the seed in the peeled processed product incapable of germination under standard germination conditions.

CONCLUSION

22. The Committee concluded that the peeled and comminuted products from GM tomatoes derived from the GM inbred line TGT7-F were as safe for human consumption as products from non-GM tomatoes.

23. In accordance with current policy, the UK considers that this/these product(s) should be labelled. However, before they can be marketed, the Company will need to comply with the requirements of the EC Novel Foods Regulation.

REFERENCES

- 1.** Submission from Zeneca Plant Sciences dated January 1997. This submission has been deposited in the British Library under its Supplementary Publication Scheme, identified as BL Sup. No. 11109.
- 2.** Submission from Zeneca Plant Sciences dated August 1994. This submission has been deposited in the British Library under its Supplementary Publication Scheme, identified as BL Sup. No.11094.
- 3.** Advisory Committee on Novel Foods and Processes: Report on tomato paste from genetically modified (GM) tomatoes, February 1995.
- 4.** Submission from Zeneca Plant Sciences dated August 1995. This submission has been deposited in the British Library under its Supplementary Publication Scheme, identified as BL Sup. No.11098.
- 5.** Advisory Committee on Novel Foods and Processes: Report on tomato paste from genetically modified (GM) tomatoes: extension to February 1995 ACNFP clearance, February 1996.

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