

ANNEX V

ACNFP REPORT ON TREHALOSE



ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

REPORT ON TREHALOSE

INTRODUCTION

1. In April 1990, the Committee was asked by Quadrant Bioresources Ltd, to examine the safety in use of trehalose (alpha-D-glucopyranosyl-alpha-D-glucopyranoside). Trehalose is intended for use in dehydrated foods as it is claimed that the quality of such foods on rehydration is improved if trehalose is added to the liquid food prior to dehydration.

PROCESS DESCRIPTION

2. Trehalose is extracted from bakers yeast which has been grown under conditions of nitrogen limitation to promote trehalose formation. Crude trehalose is crystallised from an alcohol extract of the harvested yeast and subsequently recrystallised from aqueous alcohol. At the present time a specification for "food grade" trehalose has yet to be established.

USE

3. A market for trehalose has yet to be established but possible uses are in dried foods such as milk, eggs and packet soups.

SAFETY EVALUATION

4. In its assessment of safety, the Committee recognised that trehalose is found in many conventional foods, such as yeast and mushrooms and that it is less prone to cause intolerance than lactose. Until a market is established for trehalose the Committee is unable to estimate likely intakes but felt that in some instances intakes might be significantly higher than the average intake from its presence as a food component. As trehalose is a purified chemical rather than a food the

Committee referred data submitted by the Company to the Committee on Toxicity (COT) for a toxicological evaluation.

CONCLUSIONS

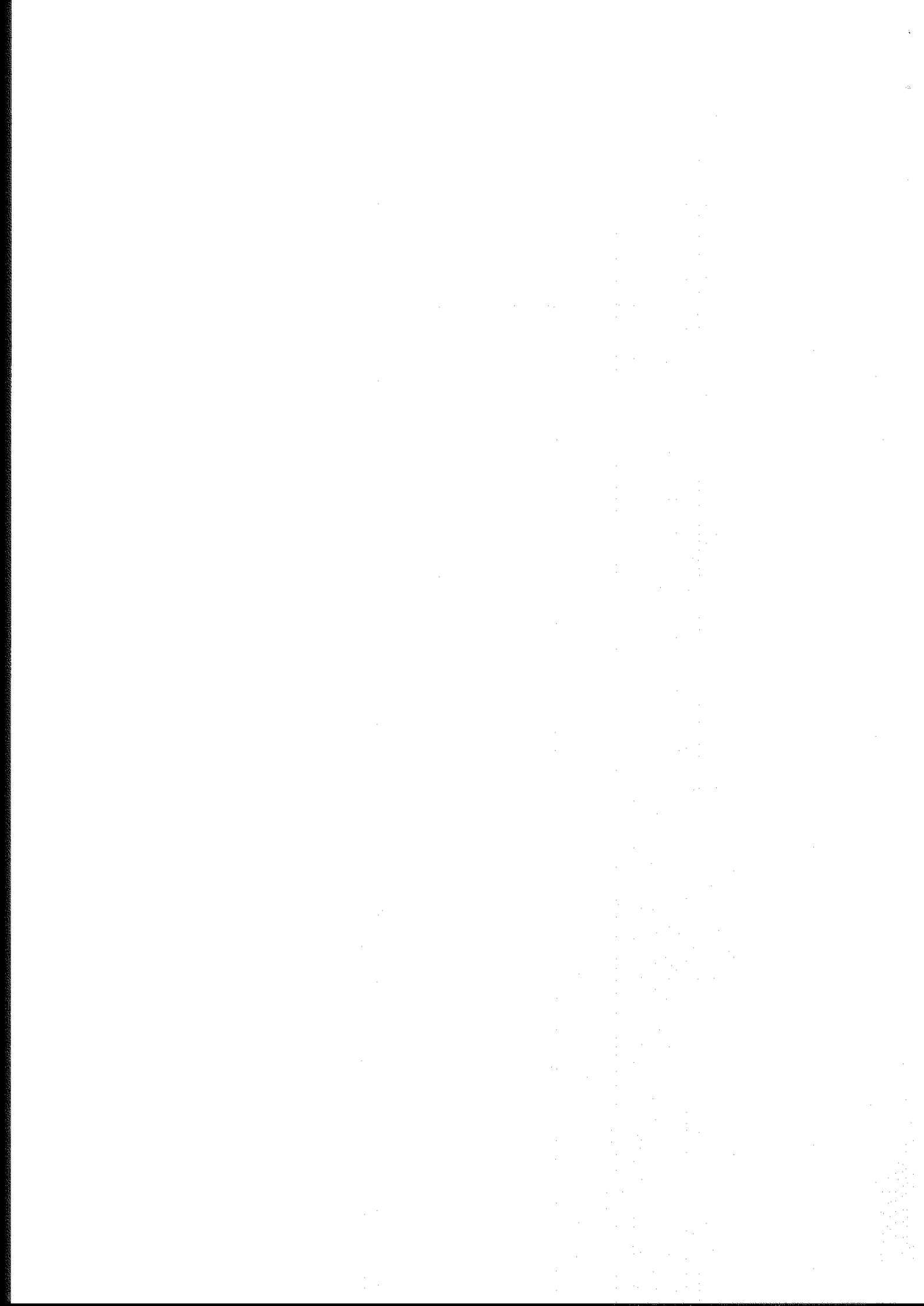
5. The Committee is satisfied that there are no food safety reasons why the addition of trehalose to food should not be acceptable provided that the recommendations of the COT are met. These are:

- an acceptable specification should be provided
- trehalose should not be used in infant formulae or follow up-milks
- there should be post-marketing monitoring to establish patterns of use.

6. Trehalose, when added to food, has a technological function and is therefore a food additive although outside current legislative controls on food additives because it does not fall within one of the controlled categories. The Food Advisory Committee, which advises Ministers on food additives, is currently reviewing trehalose.

ANNEX VI

ACNFP REPORT ON
ENZYME HYDROLYSIS OF WHOLE GRAIN



ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

REPORT ON A PROCESS FOR THE ENZYME HYDROLYSIS OF WHOLE GRAIN

INTRODUCTION

1. In April 1990, the Committee was asked by BioNova BV to examine a novel grain processing technology and the safety-in-food-use of its products. The novel process has been developed to produce from whole wheat grain, a range of products - syrups, powders and fibres - which are intended for a variety of food applications. The same technology can also be applied to a range of other grains.

PROCESS DESCRIPTION

2. Products are derived from whole wheat or other grains by enzyme hydrolysis. Cleaned grain is crushed and mixed with water before being passed through a two stage enzymatic hydrolysis. A mixture of wheat syrup (hydrolysed wheat starch), wheat fibre and insoluble protein from the wheat kernel is formed and this is sterilised and separated into solid and liquid fractions. The solid fibre fraction is removed and dried out. The liquid fraction is separated into syrup and insoluble protein. The syrup is clarified and evaporated and may be spray-dried to wheat powder.

USE

3. A market for products from the enzyme hydrolysis of whole wheat grain has yet to be identified but the following uses are proposed:

- (a) wheat syrups: replacement for sucrose in breads, jams, jellies and icecream and also for use in confectionary and canned fruit products.

- (b) wheat powders: extenders for skimmed milk in dairy products such as ice-cream, toppings, desserts and beverages; substitutes for skimmed milk and whey powders in biscuits and cakes and as a complement to milk powder in chocolate products.
- (c) wheat fibres: as an ingredient in breakfast cereals, extruded snacks, cereal bars, bread rolls and biscuits.

SAFETY EVALUATION

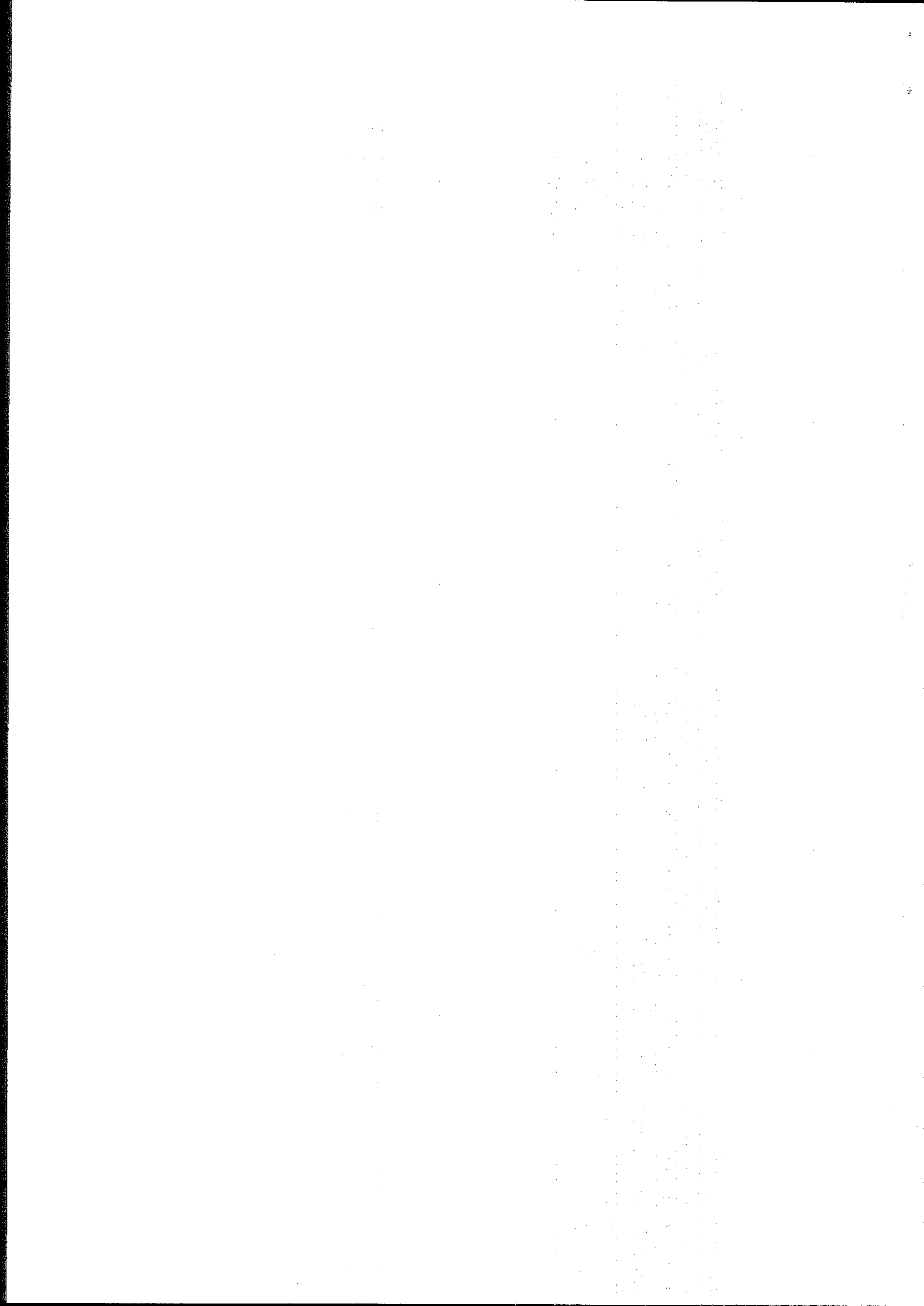
4. In its assessment of safety, the Committee recognised that all the enzymes used in the hydrolysis have been cleared by the COT and FAC for use in food. The process and specifications for products obtained from whole wheat grain were examined. The Committee noted that separated wheat fractions and products obtained from them are already used as food ingredients.

CONCLUSIONS

5. The Committee considered that there are no food safety reasons why the use of syrups, powders and fibres produced by enzyme hydrolysis of whole wheat grain should not be acceptable in food provided that:

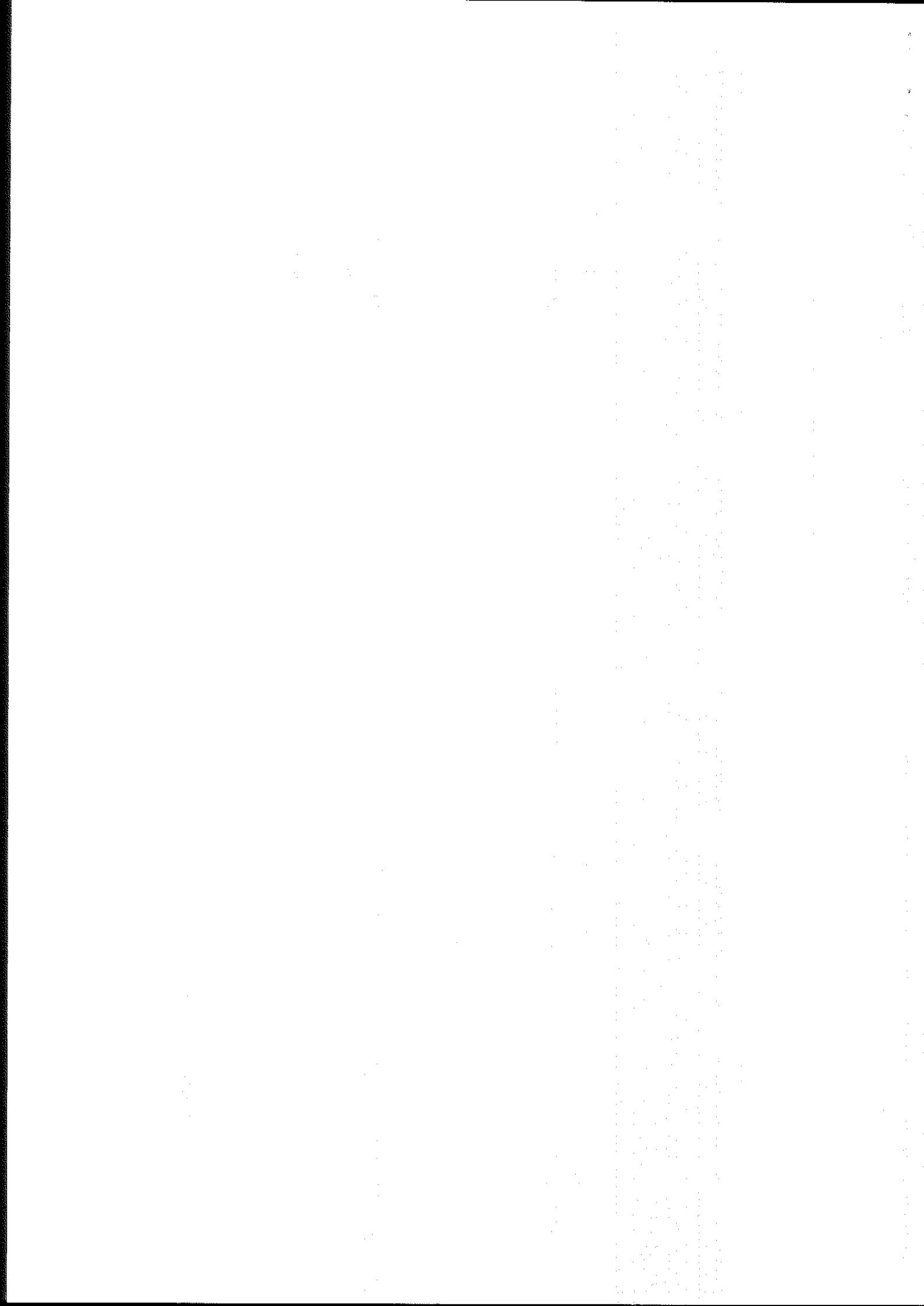
- (a) the enzymes used have been cleared by the COT for use in food;
- (b) the raw materials used are of food grade quality and levels of pesticide residues and mycotoxins, derived from the whole grain and found in the product do not exceed those currently accepted as safe;
- (c) food containing any of the products is labelled in the normal way so that those who are intolerant to wheat can avoid such foods;

(c) subject to (a) and (b) above, the Committee also considered that there are no food safety reasons why the use of syrups, powders and fibres produced by this process when applied to oats, barley, maize and rice should not be acceptable in food.



ANNEX VII

PRESS RELEASE AND ACNFP REPORT ON
ASPECTS OF FOOD IRRADIATION



11 December 1990

**JOINT ANNOUNCEMENT BY THE DEPARTMENT OF HEALTH AND THE MINISTRY OF
AGRICULTURE, FISHERIES AND FOOD**

**GOVERNMENT ACCEPTS THE ADVICE OF THE ADVISORY COMMITTEE ON NOVEL
FOODS AND PROCESSES (ACNFP) ON ASPECTS OF FOOD IRRADIATION**

The Government has accepted the advice of the ACNFP that there is no food safety reason to impose a delay between the irradiation and consumption of food. The Committee considered the results of studies by the National Radiological Protection Board before arriving at this decision. These studies showed that levels of induced radioactivity in a wide range of foods were below the natural levels of radioactivity in food within as short a time as five minutes after irradiation has taken place.

The Government has also accepted the advice of the ACNFP that the use of high energy X-ray surveillance equipment for the examination of bulk cargo containers, including consignments of food, will not adversely affect the safety of such foods. In reaching this decision the Committee had regard to a recent World Health Organisation expert Consultation which found that the use of the surveillance equipment posed no toxicological, nutritional, radiological, sensory or microbiological concerns.

Copies of the ACNFP advice have been circulated to interested organisations, and are available from the Department of Health, Room 604, Eileen House, 80-94 Newington Causeway, London SE1 6EF.

NOTES TO EDITORS

1. 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 the relevant expert bodies." It is chaired by Professor D C Burke, Vice Chancellor, University of East Anglia and is administered jointly by the Ministry of Agriculture, Fisheries and Food, and the Department of Health.

2. The advice of the ACNFP is reflected in the Food (Control of Irradiation) Regulations 1990 which are being laid before Parliament today and they are intended to come into force on 1 January 1991.

[END]

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

REPORT ON THE IMPLICATIONS OF INDUCED RADIOACTIVITY IN IRRADIATED FOODS SHORTLY AFTER TREATMENT AND THE USE OF HIGH ENERGY X-RAY CARGO SURVEILLANCE EQUIPMENT

INTRODUCTION

1. In July 1990 the Committee was asked to examine the safety of consuming irradiated foods shortly after the treatment had been applied and the separate but related topic of the safety of using high energy x-ray surveillance equipment to examine consignments of food.

2. The Committee noted that these issues had been considered by its predecessor Committee, the Advisory Committee on Irradiated and Novel Foods (ACINF). The ACINF considered that although there was no evidence that the early consumption of food exposed to ionising radiation at these energies would lead to significant exposure to induced radioactivity, in the absence of specific information it would be prudent to stipulate that food should not be consumed within 24 hours of treatment. In addition, in their 1986 report entitled "The Safety and Wholesomeness of Irradiated Foods" the ACINF had endorsed the Joint WHO/IAEA/FAO Committee recommendation that a maximum energy level of 5 MeV (million electron volts) for photon energies including x-rays, and 10 MeV for electrons, be set for all purposes.

3. Further studies by the National Radiological Protection Board (NRPB) into the levels of induced radioactivity shortly (within 24 hours) after treatment and the findings of a recent World Health Organisation expert Consultation on the use of high energy x-ray surveillance equipment make it appropriate to review the original ACINF conclusions.

DETAIL

Induced Radioactivity Within 24 Hours Of Treatment

4. The NRPB was commissioned by the Ministry of Agriculture Fisheries and Food to investigate levels of induced radioactivity in food within 24 hours of irradiation treatment. The study included calculations of induced activity at an absorbed dose of 10 kilogray (kGy) delivered

by photon energies of 5 MeV and electrons of 10 MeV, as well as that from x-ray surveillance machines operating at 10 MeV with an assumed maximum absorbed dose of 0.5 Gy.

5. The Committee noted that the NRPB had throughout assumed extreme levels of consumption by a critical individual and high concentrations of relevant elements in the food, in order to construct a 'worst case' model. The dose delivered by high energy surveillance equipment, at 0.5 Gy, is similarly pessimistic. The NRPB had concluded that even under such extreme conditions, "the induced activities in the wide range of foodstuffs considered are below the level considered to be of concern to regulatory authorities".

High Energy X-Ray Surveillance Equipment

6. Many countries permit the use of x-rays to examine food raw materials and finished products for foreign bodies. Such equipment uses relatively low energy x-rays and apply very low doses to the food. United Kingdom legislation has since 1972 excluded the use of such machines from the general prohibition on food irradiation, provided they have an energy level not exceeding 5 MeV and do not impart a dose greater than 0.5 Gy. Such devices have been in routine use throughout the World for many years.

7. However, more recently, with an increase both in the volume of international traffic and the need for effective surveillance a requirement was developed for fast and effective surveillance equipment suitable for use with bulk cargo containers. New systems have been developed which employ x-rays with energy levels in excess of 5 MeV. As a number of national authorities wished to use the new x-ray equipment to screen cargo, including consignments containing food, the countries concerned sought the advice of the WHO as to the safety of such operations. The WHO consequently convened an expert Consultation meeting to consider the facts and express a view on safety issues.

8. The WHO considered the most extreme situation envisaged and sought advice on the use of 10 MeV x-rays and a dose of 0.5 Gy. The experts consulted were asked to consider the effects that exposure to this level would have on foods.

9. The expert group found that there were no toxicological, nutritional, radiological, sensory or microbiological concerns and concluded that the use of such equipment would not adversely affect the safety of foods.

CONCLUSION

10. The Committee is satisfied that there is no food safety reason why a restriction should be placed on the sale of freshly irradiated foods. In reaching this conclusion the Committee took account of the recent calculations of the NRPB and in particular it noted the finding that at a dose of 10 kGy, applied at the internationally recognised maximum energy levels for food irradiation (5 MeV photons and 10 MeV electrons) levels of induced radioactivity in a wide range of foods were below the natural levels as short as 5 minutes after irradiation.

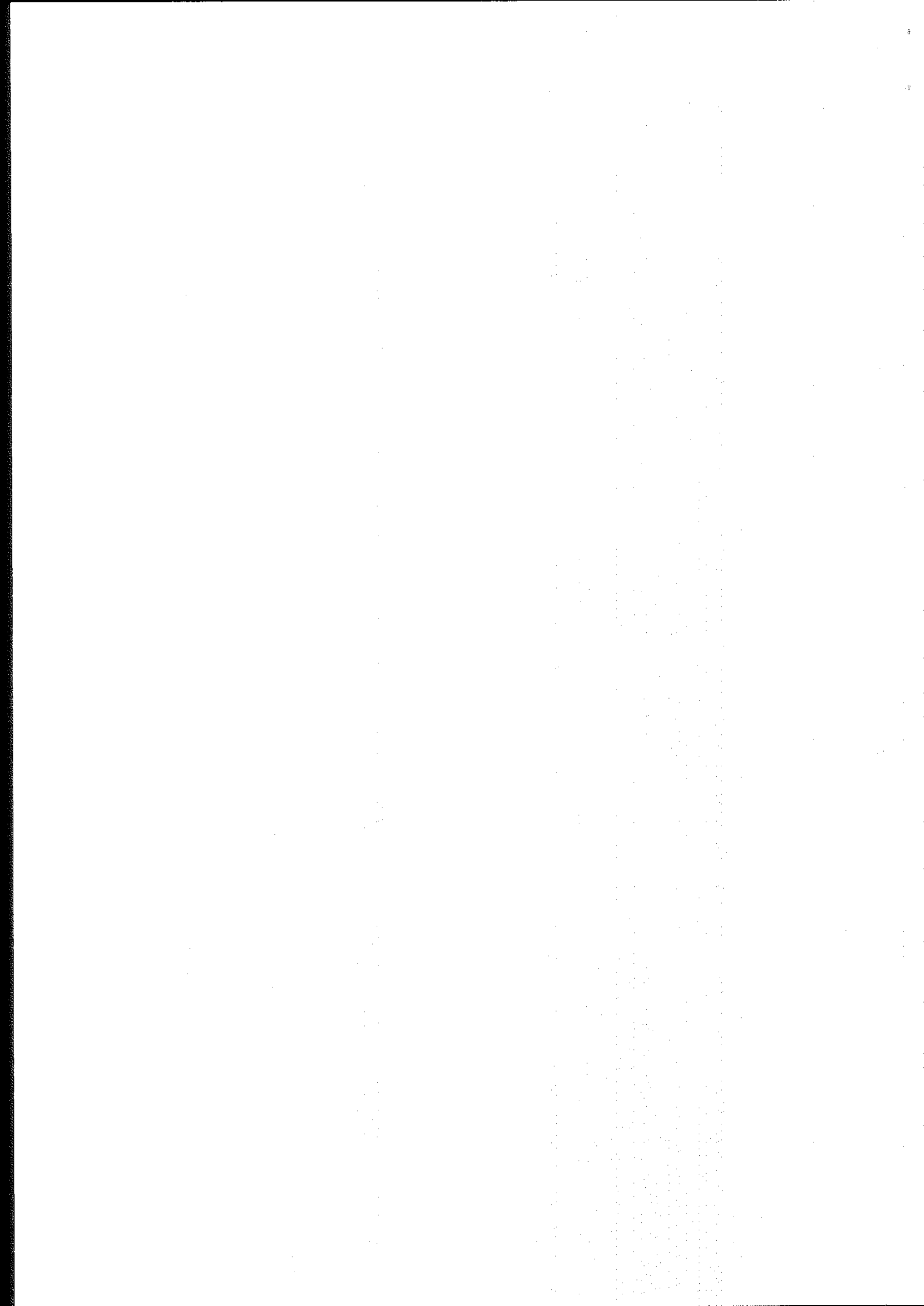
11. The Committee is similarly content to endorse the conclusion of the WHO expert consultation group that x-ray surveillance equipment operating at a maximum energy level of 10 MeV and imparting a dose no greater than 0.5 gray would not adversely affect the safety of foods. In reaching this decision the Committee found it of assistance that the recent studies of the NRPB had included an assessment of induced radioactivity at this energy level and dose which found no radiological safety concerns. It should however be made clear that the Committee's advice relates only to high energy x-ray systems and does not extend to other measurement or inspection devices using corpuscular radiations, for which a maximum energy level of 5 MeV remains appropriate.

References

1. Food safety aspects relating to the application of x-ray surveillance equipment : Memorandum from a WHO meeting; Bulletin of the World Health Organisation (WHO 1990) Vol68 No3 pp 297-301.
2. A theoretical study of the radiological consequences of food irradiation, to be published late 1990 in the National Radiological Protection Board 'Technical Report' Series available through HMSO bookshops.

ANNEX VIII

REPORT OF ACNFP WORKSHOP



ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES (ACNFP)

NOTE OF WORKSHOP HELD ON 9 OCTOBER 1990

INTRODUCTION

The ACNFP Workshop on consumer concerns arising from the use of genetic modification in the food chain was held at the Hertfordshire Moat House Hotel, Markyate on 9 October 1990. A list of participants is at Annex 1.

In his introductory remarks the Chairman, Professor Burke, outlined the history of the ACNFP and the reasons for holding the workshop. He explained that the Committee believed that if there was a failure to explain the basis for the clearances given, it would not carry the confidence of the general public or opinion formers.

Four short talks were given by Professor Beringer, Professor Hicks, Mr Davis and Mrs Foster which highlighted respectively some of the scientific, safety, legislative and consumer perception aspects of genetic modification relevant to the food industry. The discussion which followed centred upon the points raised by the speakers and in previously circulated background papers which are listed in Annex 2.

It was noted that the reaction to the recent tryptophan problem which has had so much publicity in the USA has highlighted the differences in perception between scientists and consumers. In seeking an explanation, most consumer concern has focused on the genetically modified organism involved and there has been a call for the US Food and Drug Administration to suspend licencing any genetically engineered products until there has been a full public enquiry. Scientific attention, on the other hand, has concentrated on both the changes in downstream processing and the genetically modified organism.

Expert advisory committees were seen to have an important role in assessing whether genetic modification procedures result in

the transfer of the target genes only and, more generally, in ascertaining that any risks arising from the transfer of genes are reduced to the minimum. However, if every new product that could be derived from the use of genetic modification were to be subject to detailed scrutiny by expert advisory committees, then it was observed that there could eventually be problems with resources, and attendant implications for safety. It was therefore necessary over time to establish general principles for reviewing safety of genetically modified products.

It was pointed out that there is an assumption among some consumers that existing foods are absolutely safe and that therefore novelty itself is a cause for concern. When a new food is introduced, social acceptability is always given major consideration by the manufacturer. Consumers show extreme concern about safety and a lack of understanding fuels their concern. This is demonstrated by the way in which, for example, consumers perceive the hazards from food additives to be greater than those from natural toxicants with which they are less familiar. Genetic modification is little understood by many consumers and consequently gives rise to consumer concern. Unfortunately, public understanding often only occurs after debate provoked by particular problems which receive widespread publicity.

The UK system of government expert advisory committees on genetically modified organisms was seen to be valuable, with its opportunities for consultation between committees and use of a wide range of independent experts. Some fear was expressed that the present system may be weakened with the introduction of EC procedures, particularly as the practice in many other member states is to rely much more on appraisal by single experts.

It was noted that a clear legislative framework is important in allaying the fears of consumers and benefits both the consumer and industry. When exposure to a substance is involuntary, consumers tend to demand higher levels of reassurance. The case of Alar had demonstrated the difficulty of maintaining consumers' confidence despite the scientific evidence of

negligible risk. Involuntary exposure to any genetically modified organism could raise the same fears.

SESSION 1

The first part of the discussion concentrated upon the reasons for the apparent loss of consumer confidence in scientists and regulators and the ways in which this could be redressed.

Participants agreed that consumer confidence in the way that decisions are made would be increased by more openness. Public information about genetically modified organisms and the foods in which they are used would allow a more informed choice to be made.

The differences between scientific assessment of risk and the risk perceived by consumers were examined and it was suggested that greater dialogue is needed between consumers and scientists in order to understand each others' concerns. Consumers' confidence in scientists and their assessment of risk has decreased in the past 30 years, especially following events such as Chernobyl. Moreover, scientists are no longer perceived to be impartial and are thought by consumers to be influenced by commercial and political interests. Consumers need to understand that scientists cannot give absolute guarantees of the extent of risk. Increased confidence could be brought about through greater access to information and by letting the consumer see the process by which scientists on expert advisory committees reach decisions on the probable risk.

It was pointed out that "consumer concerns" and "consumer attitudes" are different. "Consumer concerns" are underlying themes such as the environment or the developing world. "Consumer attitudes" fluctuate and can be influenced by the media or pressure groups. Psychological studies on consumer attitudes to risk have shown that perception depends on how people edit the information that they receive and this can be heavily influenced by the media. However, the level of risk

thought acceptable differs between individuals according to their family and educational background. Educating the public about genetic modification would allow consumers to make more informed judgements.

Risks and benefits were shown to involve value judgements which are strongly influenced by moral, ethical and religious beliefs. There was some discussion of whether it is appropriate for an expert scientific committee to make such judgements. Scientific committees need to be able to identify the ethical issues but should not give advice or judgments on such issues.

SESSION 2

Participants were invited to discuss ways in which existing procedures could be altered to increase openness.

It was thought that publicising the basis and reasoning for ACNFP decisions could facilitate the development of consumer understanding. Wide consultation was suggested for "first of a kind" decisions and possibly for all applications. This might be achieved, for example, through a register system, comparable to that which will be used for the Advisory Committee on Release into the Environment (ACRE), and would allow public representations to be made. It was proposed that membership of the ACNFP should be widened to include a lay member although careful consideration would have to be given to the way in which such interests were represented.

"Fourth Hurdle" issues, including the establishment of a case of need, were discussed, although the group was divided as to whether such considerations should play any role in the approval process. The Layfield Report which considered tolerability of risk was cited. This stated that where there is a wider public danger, there is a need to take risk, benefit and ethics into consideration. For genetic modification issues, scientists may need to advise on benefit. The broad consensus was that general market need cannot be anticipated by regulations but that

Ministers can respond to public concerns. Socio-economic implications could be drawn to Ministers' attention by the ACNFP, but as the Committee is presently constituted, it is not qualified to do this.

SESSION 3

The final discussion was aimed at drawing up a list of proposals from the workshop for presentation to Ministers. These are summarised below :

Committee issues

1. Membership of the ACNFP should be broadened to increase transparency.
2. Consideration should be given to allowing observers at ACNFP meetings.
3. A register of applications to the ACNFP should be published.
4. The ACNFP should continue to hold press briefings.
5. More information on the ACNFP should be available, eg how it reaches decisions; how it interacts with other advisory committees, especially the FAC.
6. Should the ACNFP's advice differ from that of equivalent bodies in other countries, the Government should make a particular effort to explain why.

Consultation

7. There should be greater consultation particularly on "first of a kind" proposals. (ACNFP advice to Ministers could include a recommendation on the need for wider consultation).
8. The opportunity for public representations should be built into any statutory scheme for control of novel foods.

Education

9. Government should produce educational material on biotechnology.

Research

10. Government should commission research into consumer perceptions and food choice.

Other issues

11. A guidance note defining the extent of commercial confidentiality should be prepared.
12. The FAC guidelines for the labelling of genetically modified foods should be published.

LIST OF PARTICIPANTS

Dr M Ashwell	Science Director, British Nutrition Foundation; FAC Member
Dr D Atkins	MAFF; FAC Scientific Secretary
Mr J Bainton	MAFF
Dr A C Baird-Parker	Head of Microbiology Division, Unilever Research; ACNFP member
Dr P Baker	Dept of Trade and Industry
Professor J Beringer	University of Bristol; ACRE Chairman
Ms C Brock	Dept of Health; ACNFP Admin Secretary
Professor D C Burke	Vice-Chancellor, University of East Anglia; ACNFP Chairman
Mr T Davis	MAFF
Dr W H B Denner	MAFF
Mrs A Foster	National Consumer Council
Professor D Georgala	Director, AFRC Institute of Food Research; FAC Member
Dr I R Hart	Imperial Cancer Research Fund
Mrs S Hattersley	Dept of Health
Professor R M Hicks	United Biscuits UK Ltd; FAC Member
Ms J Hill	Green Alliance; ACRE Member
Mr J Horton	MAFF; FAC Admin Secretary
Dr D A Jonas	MAFF; ACNFP Scientific Secretary
Dr D King	Genetics Forum
Dr P Kearns	Dept of the Environment
Professor Sir Hans Kornberg	Master of Christ's College, University of Cambridge; ACGM Chairman
Mr R Manley	Director of Trading Standards, Cheshire County Council; FAC Member
Dr H MacFie	AFRC Institute of Food Research
Ms K McColl	Consumers Association
Mrs E Morris	MAFF
Professor B Moseley	Head of the Reading Laboratory, AFRC Institute of Food Research; ACNFP Member
Dr E Nickless	Cabinet Office
Professor T O'Riordan	University of East Anglia
Mrs S Payne	Consumer Panel
Miss R J Rasaiah	MAFF
Rev D Reindorp	Vicar of Waterbeach

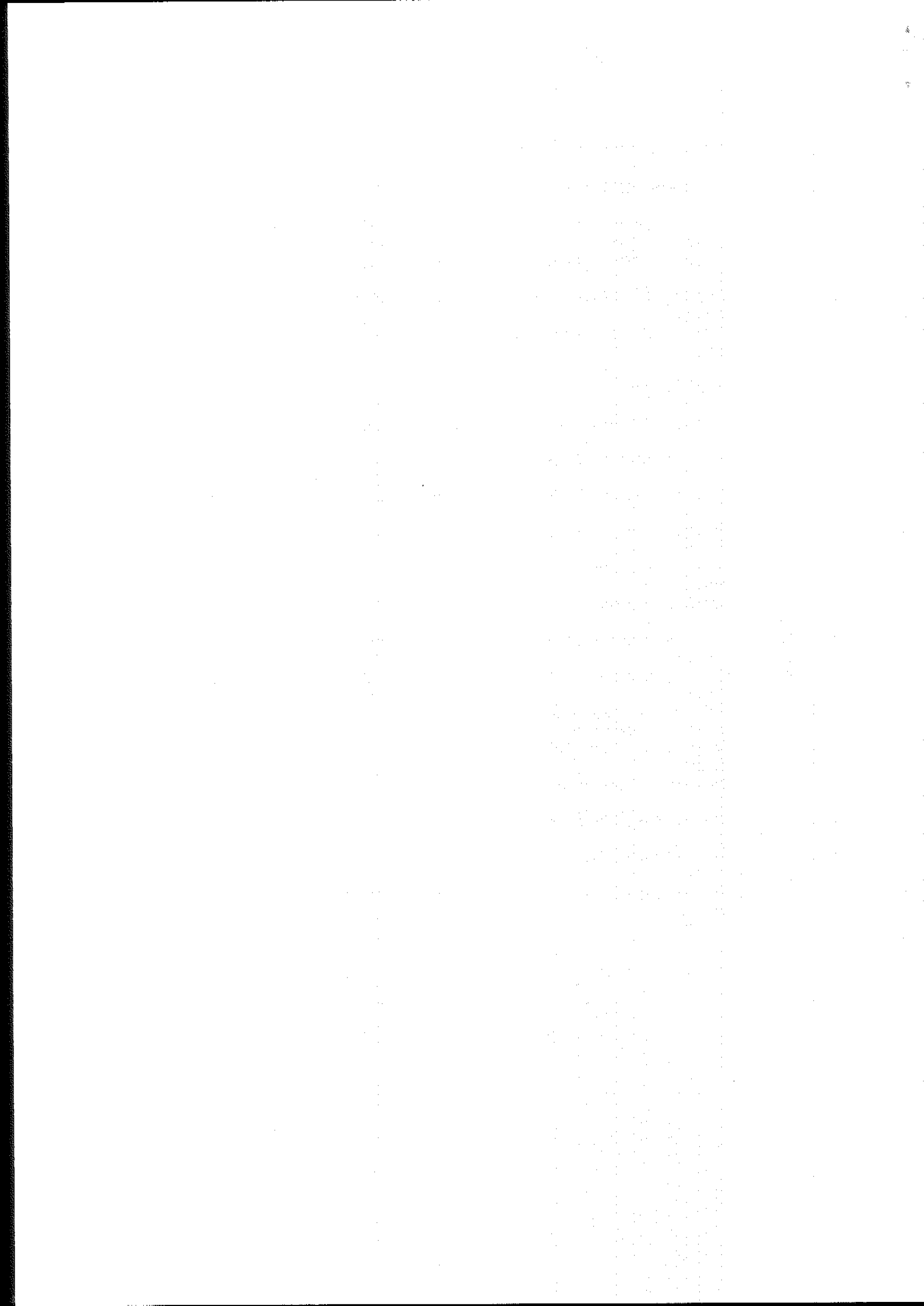
Professor P Richmond	Head of the Norwich Laboratory, AFRC Institute of Food Research; ACNFP Member
Professor L Roberts	University of East Anglia
Dr P J Rodgers	ICI Biological Products; ACNFP Member
Mrs B Saunders	Consumers in the European Community Group (UK); FAC Member
Dr R Singh	Dept of Health; ACNFP Medical Secretary
Professor J E Smith	University of Strathclyde; ACNFP Member
Professor D A T Southgate	AFRC Institute of Food Research; ACNFP Member
Dr R Straughan	University of Reading
Mr A J Taylor	Health and Safety Executive; ACGM Secretary
Professor R Walker	University of Surrey; ACNFP Member

Acronyms

ACGM	Advisory Committee on Genetic Modification
ACNFP	Advisory Committee on Novel Foods and Processes
ACRE	Advisory Committee on Release into the Environment
FAC	Food Advisory Committee

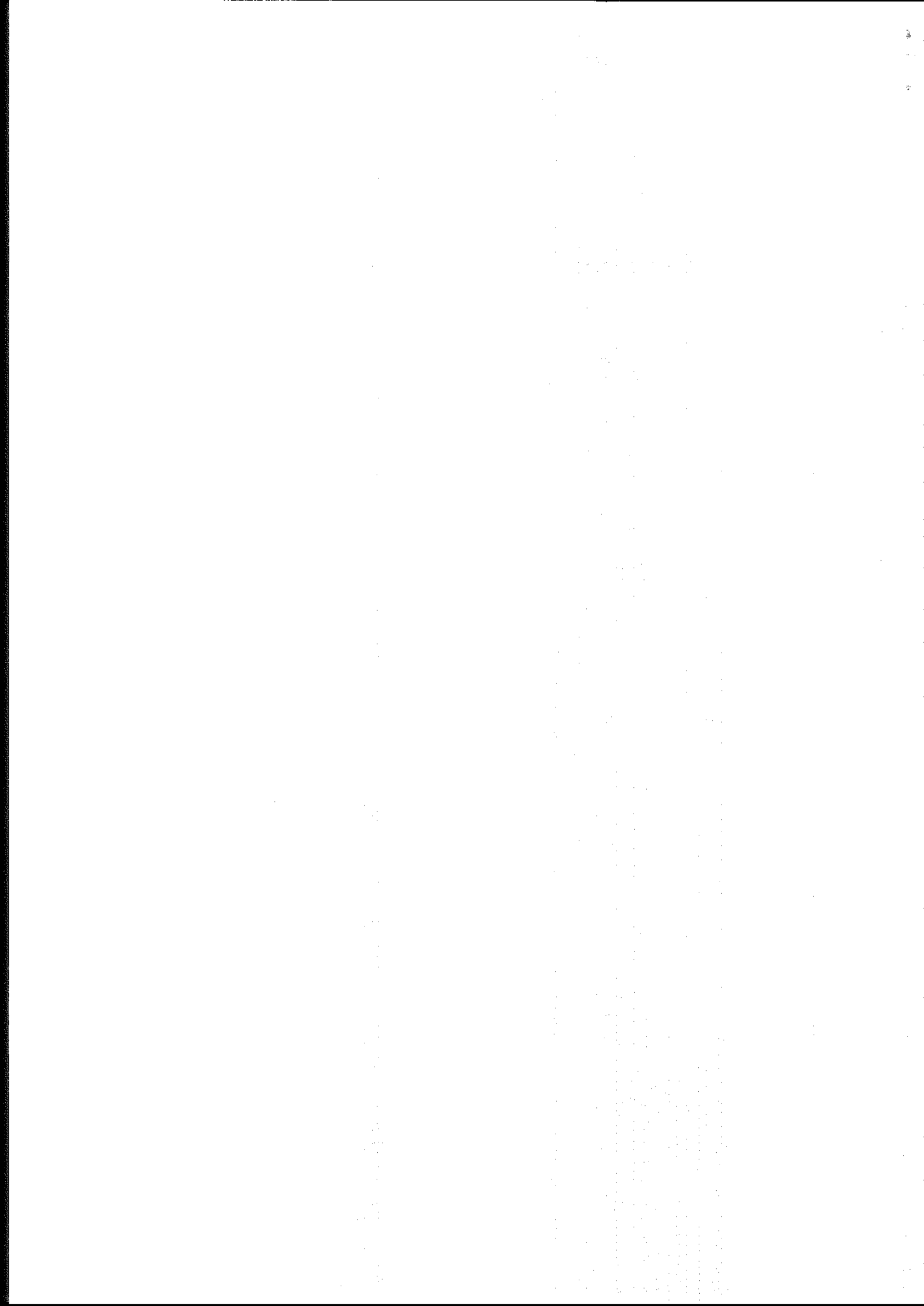
LIST OF BACKGROUND PAPERS

1. The Genetic Programming of Industrial Micro-organisms
(D A Hopwood, 1981)
2. Guidelines on the Assessment of Novel Foods
(ACNFP)
3. Novel Foods: Problems of Safety and Acceptability
(R M Hicks)
4. Labelling of Foods Produced Using Genetically Modified
Organisms
(MAFF)
5. E C Legislation
(MAFF)
6. Protection of Genetically Modified Animals
(MAFF)
7. Human Health and Safety
(HSE)
8. Novel Foods - Food Safety Act and Draft EC Regulations
(MAFF)
9. Biotechnology and the Consumer
(B Saunders)
10. Risk and Perception
(P Richmond)
11. Public Information
(R Manley)
12. Consumer Concerns and Scientific Advice
(T O'Riordan)
13. The Genetic Manipulation of Plants, Animals and Microbes
(R Straughan)
14. Need for a National Bioethics Body
(Nuffield Foundation)
15. Procedures for Providing Advice
(T Gorsuch)
16. Food Advisory Committee
(MAFF)
17. Genetically Modified Foods
(MAFF)
18. Consumer Perceptions
(H MacFie)
19. Consumer Perceptions of Food Related Issues
(M Ashwell)



ANNEX IX

LIST OF ACNFP MEMBERS AND SECRETARIAT
FOR 1990.



MEMBERSHIP OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

CHAIRMAN

Professor Derek C Burke, BSc, PhD, HonLLD
Vice-Chancellor, University of East Anglia

MEMBERS

Professor G E Adams, BSc, PhD, DSc, FACR
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Dr P J Rodgers, MA, DPhil
Research and Regulatory Affairs Manager at ICI Biological
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Professor J E Smith, BSc, MSc, PhD, DSc, FIBiol, FRSE
Head of the Applied Microbiology Division, Department of
Bioscience and Biotechnology, University of Strathclyde

Dr J W G Smith, MD, FRCP, FRCPath, FFPHM, FIBiol, DipBact
Director of the Public Health Laboratory Service, London

Professor D A T Southgate, BSc, PhD, MIBiol
Head of the Nutrition Division of Norwich Laboratory,
Agricultural and Food Research Council Institute of Food
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for Cancer Research, Christie Hospital and Holt Radium
Institute, Manchester

Professor P Turner, MD, BSc, FRCP, FFPM
Professor of Clinical Pharmacology, St Bartholomew's Hospital
Medical College, University of London

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

SECRETARIAT

Medical - Dr R Singh
Department of Health

Scientific - Dr D Jonas
Ministry of Agriculture, Fisheries and Food

Administrative - Mrs M Fry to September 1990

Ms C Brock from October 1990
Department of Health