ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

ANNUAL REPORT 1990

DEPARTMENT OF HEALTH,
MINISTRY OF AGRICULTURE,
FISHERIES AND FOOD.

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES
SECOND ANNUAL REPORT - 1990

INTRODUCTION

1. In October 1988, Ministers announced that the Advisory Committee on Novel and Irradiated Foods (ACINF) would be reconstituted as the Advisory Committee on Novel Food and Processes (ACNFP) to reflect more accurately its interest in the rapidly developing area of food biotechnology. The Committee meets four times a year and its Secretariat provided jointly by officials of the Department of Health and the Ministry of Agriculture, Fisheries and Food.

2. The Committee 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".

3. This second Annual Report covers the 4 meetings held in 1990 and a workshop organised in October 1990 (details of which appear later, paragraph 9). The report follows the same format as the first (1), which covered proceedings to the end of 1989.

SUBMISSIONS/TOPICS CONSIDERED

4. During 1990, the Committee considered a number of submissions and topics, some which were carried over from 1989 and were described in the first annual report (1). Brief details are also given of how topics finalised by the Committee in 1989 have progressed.

5. Topics finalised by ACNFP in 1989 which required further action by the Committee or others in 1990; further details of these may be found in the previous annual report (1):-

a. Genetically Modified Bakers Yeast

The Committee's views were passed to Ministers who gave their clearance for the use of the product. A press release was issued on 1 March 1990: a copy appears as Annex I to this report. The Committee considered subsequently that this brief press release was inadequate: its brevity giving rise to concerns about the Committee's lack of openness and to suggestions that the assessment process had been inadequate.In addition a numbe of newspapers expressed concerns about the use of "man-made" organisms in food. In order to meet these concerns the Committee has:

1. Reviewed the procedures leading to press releases in order to ensure inclusion of adequate information about the approval process and the product in question.
2. Organised a workshop , with participants drawn from a wide range of groups, to discuss issues surrounding public perception of novel foods (details of whic may be found at paragraph 9).

Data relating to this submission have been deposited with the British Library. The reference section of this report contains details of how these data may be viewed.

b. Code of practice on taste trials for beers produced from genetically modified yeast

i. The Committee has entered into detailed correspondence with the brewing industry about the need for referral of taste trials to ethics committees and requested further details of their trials.

ii. The Committee understands the widespread concerns about the need for ethical guidelines in any taste trials involving products from genetically modified organisms. In addition to trials on beers a request was received for guidance on taste trials of genetically modified tomatoes (see paragraph 6e). These two examples demonstrated to the Committee the need for establishment of general procedures for such taste trials, and the Committee is proceeding to establish suitable guidance that includes the approval by ethics committees and long term maintenance of records.

c. Fructose syrup containing dextrans

The Committee's views were forwarded to Ministers who cleared the use of this produ in foods. A press release was issued on 6 September 1990; a copy appears as Annex to this report.
Data relating to this submission have been deposited with the British Library. The reference section of this report contains details of how these data may be viewed.

d. Chymosin enzyme from a genetically modified source organism

In 1989 the Committee forwarded its advice to the Food Advisory Committee (FAC). Th FAC has considered this item and submitted its advice to Ministers. A press release announcing Ministerial clearance for the enzyme derived from a transgenic *Kluyveromyces lactis* was issued on 17 January 1991; a copy appears as Annex III to t report, together with a copy of the ACNFP advice.

6. New items that the Committee has considered in 1990 on which its views have be finalised.

a. A second Chymosin enzyme from a genetically modified source organism

i. Traditional cheese manufacture has involved the coagulation of milk by an enzy preparation (rennet) derived from the stomach of calves. A submission was received from a second manufacturer of a chymosin enzyme derived from transgenic *Aspergillus niger var. awamori* (a different source organism to that considered in 1989). Enzym are regarded as food additives and thus fall within the remit of the Food Advisory Committee (FAC). That Committee obtains advice on safety from the Committee on Toxic of Chemicals in Food, Consumer Products and the Environment (COT). However, in view the fact that the source organism for this particular enzyme had been genetically modified, the FAC also sought the advice of the ACNFP as to whether there were any safety concerns arising specifically from the particular genetic modification proced used.

ii. The ACNFP has considered this aspect of the submission and passed its advice t the FAC, which will be considering , among other matters,any labelling requirements.

b. Passion fruit seed oil

i. The Committee received a submission requesting clearance for the use of oil obtained by the cracking and pressing of passion fruit seeds followed by standard refining techniques. The oil would be used in speciality foods and salad dressings. Because passion fruits, particularly immature fruits, have long been known to contain cyanogens (compounds containing cyanide or having the ability to release it) the Committee considered the possibility of high levels of cyanogens being present in the oil. However, seeds are normally consumed with passion fruit and data were available to indicate that toxicologically significant amounts of cyanogens are not present in the seeds of passion fruit at any stage of maturity or in the oil, indicating the flesh to be the likely cyanogen-containing part.

ii. The Committee concluded that the consumption of passion fruit seed oil would be acceptable providing it met a specification including maximum levels of cyanide, heavy metals, mycotoxins and fatty acid composition. A report of the Committee's advice was passed to Ministers and is attached as Annex IV to this report.

c. Trehalose

i. The Committee was requested by the manufacturers to consider the safety of trehalose, a disaccharide of glucose (alpha, alpha-linked), derived from yeast. Trehalose is claimed to improve the quality of dehydrated food such as milk powder and packet soups upon rehydration. The Committee noted that trehalose is present naturally in many foods such as mushrooms and is reported to produce less intolerance than certain other disaccharides. An opinion on the safety of trehalose was sought from the COT which advised that trehalose was acceptable provided that it was not used in infant formulae and follow-up milks, that an acceptable specification was produced and that there was post-market monitoring to establish patterns of use.

ii. Although trehalose is proposed for addition to foods to fulfil a specific technological function, that function is not covered by any specific legislation at the present time. However, in view of its proposed use as an additive rather than a food the FAC has primary responsibility in reviewing this product. The FAC will draw on advice from ACNFP and COT in formulating advice to Ministers. The ACNFP's contribution to this is at Annex V of this report.

d. Hydrolysed Whole Grain

i. The Committee reviewed a submission relating to the safety in use of products such as syrups and powders produced by the enzymic hydrolysis of whole grain. The claimed advantages of enzymic hydrolysis of whole grains as opposed to chemical hydrolysis following milling, is that constituents of all parts of the grain appear i the product giving improved flavour and nutritional content. The submitted data referred only to wheat and the Committee considered in particular whether these coulc be extrapolated to other crops. The views of COT were sought on the safety of one of the enzymes (a pullulanase) used. The COT considered that this enzyme was provisional acceptable for use in food; the other enzymes had all been previously evaluated and classified as provisionally acceptable by the COT.

ii. The Committee considered that the process could be cleared for food use on cereals commonly consumed in Europe. A report of the Committee's view has been forwarded to Ministers and appears as Annex VI to this report .

e. Tasting of Genetically Modified Tomatoes

i. A common variety of tomato had been genetically modified to produce reduced levels of an enzyme (polygalacturonase) involved in the softening process. The development programme had reached a stage where it was appropriate to investigate the effect of the modification on the organoleptic properties of the fruit. The producers had developed a protocol for an 'in house' taste trial and the Committee was asked tc endorse the protocol.

ii. The Committee considered that the protocol was satisfactory and endorsed the taste trial. The Committee also considered that there would not be any concerns regarding taste trials of other varieties of tomatoes produced by identical technique

iii. The Committee considered it would be useful if general guidelines relating to ethical as well as safety criteria for the conduct of taste trials of foods from genetically modified sources were produced. This guidance will be formulated in 199

f. Irradiation of Food

i. The Committee was asked to consider whether it was acceptable to permit the use of X-ray surveillance machines operating to a maximum energy level of 10 million electron volts (MeV); and whether there was a need to maintain the advice of its predecessor Committee, ACINF that there should be a minimum of 24 hours between the irradiation treatment of food and its consumption.

X-ray Surveillance Equipment

ii. UK food legislation has for more than 20 years controlled the operation of X-ray surveillance equipment when it is used for the inspection of cargoes containing food. Since 1972 the maximum energy of these machines has been set at 5 MeV with the maximum absorbed dose 0.5 Gray (Gy). However, recently there has been an increased need for effective security at ports and borders. Equipment has been developed which can be used to inspect whole cargo containers. These machines operate at energy levels of up to 10 MeV but still only impart doses at or below 0.5 Gy. The Committee considered data from the National Radiological Protection Board (NRPB) on the levels of induced radioactivity in food inspected at 10 MeV and thereafter endorsed the view of a World Health Organisation Consultation, that the use of X-ray cargo surveillance equipment operating at up to 10 MeV and dose levels of 0.5 Gy, would not adversely affect the safety of food.

24 Hour Rule

iii. The ACINF had recommended that food should not be consumed within 24 hours of irradiation treatment on grounds of prudence, because they had no data on levels of induced radioactivity at times less than 24 hours. The NRPB had recently investigated levels of induced radioactivity in a wide range of food stuffs at times within 24 hours of irradiation. These studies had indicated that although a small amount of radioactivity might be induced in food by high energy irradiation treatment this would decay rapidly and represent no more than natural background levels 5 minutes after irradiation.

iv. The Committee considered these data and concluded that there were no human health or safety grounds to justify continued recommendation of the 24 hour rule.

v. The report of the Committee's advice on these issues was forwarded to Ministers and appears as Annex VII of this report. The advice was incorporated into the Food (Control of Irradiation) Regulations 1990 (2), which came into force on 1 January 1991

7. The Committee also considered several items where it has not yet concluded its deliberations:-

a. Transgenic Animals

i. In 1989 the Committee considered general issues associated with the consumption food products derived from transgenic animals. This year two specific submissions we received relating to proposals for the food use of animals in which genetic modification to incorporate human genes (for medicinal products) had failed and also for the food use of their offspring. The success rate for producing transgenic anima is very low, below 1%, and the companies wished to sell into the food chain animals which did not display transgenic characteristics. In reviewing these applications th Committee took the opportunity to consider, in principle, the food safety issues rais by the potential sale for food use of any animals from a breeding programme designed produce transgenic organisms.

ii. The Committee found it useful to distinguish between four classes of animals arising from such experiments:

a. Animals in which the gene is incorporated and expressed as intended; these represent about 0.1% of the total number of animals.

b. Animals incorporating the gene but not expressing it; these represent around 1% of the animals .

c. Animals in which the human gene cannot be detected even by sensitive techniques such as the polymerase chain reaction (PCR). The majority of these animals will be truly negative. But it is possible that in some animals the gen may have been incorporated only into certain cells (mosaicism) which were not i the test sample. However, any negative results from second or subsequent generations will be unequivocal.

d. Animals which have been bred from first generation experimental animals and in which the human gene is lacking.

iii. Animals in class d and class c (after one generation) are normal animals and there is no reason why they should not be released into the food chain. However, the Committee is aware of the considerable public concern regarding ethical and moral aspects arising from the food use of animals involved in genetic modification work, an has offered advice to Ministers as to ways in which this sensitive issue might be take forward.

b. Ohmic Heating

i. When foods containing small solid pieces (eg vegetable soups and dishes such as chilli con carne) are heated by conventional methods to sterilise them prior to packaging there are difficulties in obtaining even heating. This often results in an overcooking of the exterior of solids. Ohmic heating works by passing an alternating electric current through the food which may or may not have been pre-cooked traditionally and since it depends on resistance to current flow to generate heat it results in more even heating.

ii A submission has been received for clearance of this process. The Committee considered in particular: the nutritional implications, the possible effects due to migration of electrode materials, and electrolytic effects. The topic has been referred to COT for their advice on safety matters, before final recommendations are formulated.

c. Quinoa

i. Quinoa is a South American grain crop which is being developed as a potential crop for the UK. Some quinoa is currently sold in the UK and is regarded as a possible alternative to rice. Quinoa has a high nutritional content, but in its unprocessed state contains saponins. Saponins are found in many foods; they are natural detergents with a bitter taste. The low levels usually found are tolerated without adverse effects, though high levels have been associated with toxicity, producing effects such as the breakdown of cells and changes in cholesterol levels.

ii. The Committee decided it would need further information, particularly on the biological significance and content of the saponins in quinoa as marketed in the UK, before it could make any recommendations. The Committee Secretariat is gathering further data.

d. Honey containing pollen from Genetically Modified plants

i. With the increase in research on genetically modified plants eg. to produce p or pesticide resistant strains, there is the possibility of pollen from plants containing novel genes getting into honey and then being consumed. Initial advice received by the Committee was that it was unlikely that novel genes would be expres in pollen in honey but that there was little or no information on other areas of concern, such as genetic transfer to gut microflora.

ii. The Committee believed that any food safety risks from the planned release of genetically modified plants cleared by the Advisory Committee on Releases to the Environment (ACRE) would be minimal. Nevertheless it is seeking further information the areas of possible concern before coming to any conclusions. The ACNFP is also continuing to monitor applications to ACRE which could involve the release of polle from genetically modified plants, under circumstances when pollen might be transfer by bees into honey for human consumption.

iii. The Committee recognised that there were potential food safety implications if food producing plants were cross-pollinated by pollen from genetically modified pla It will be returning to this topic at a later date.

e. Lupins

i. A submission was received requesting clearance for the use of the narrow leav lupin (*Lupinus angustifolius*) in food. This has not been widely consumed in Europe but is being developed as a commercial crop in Australia.

ii. The Committee has sought the advice of the COT on the toxicological data.

8. Guidelines

As described in the first annual report, the Committee decided to produce guidelines t assist those wishing to make submissions to the ACNFP. These guidelines include a decision-tree approach to identify the data needed to enable an assessment of the acceptability of a novel food or process. The guidelines have recently been published (3) following consultation and revision. The Committee hopes that the guidelines will widely used in formulating applications , and that such use will lead to their continu refinement and modification.

9. Workshop on Consumer Attitudes to Novel Food

i. The Committee organised an informal workshop in October 1990. This was attended by about 40 people from a range of backgrounds including industry, consumer and environmental groups, and regulators. Wide ranging discussions took place on many aspects of novel food production and marketing and a broad agreement was reached on most areas. A number of recommendations, relating to provision of information about the work of the ACNFP, increased openness of ACNFP meetings, research into consumer perceptions and improved consultation procedures, have been passed to Ministers for their consideration.

ii. A report of the workshop proceedings is attached as Annex VIII to this report.

OTHER MATTERS

10. Drug resistance markers

In order to select organisms which have been genetically modified successfully, scientists often include a marker gene conferring resistance to specific chemicals (eg antibiotics) as part of the modification procedure. As certain microorganisms have the ability to exchange genetic material, the potential for dissemination of these marker genes needs to be considered. Under both UK regulations and EC directives relating to the release of genetically modified organisms (GMOs), all releases of GMOs, including those involving organisms carrying drug resistance, are considered on a case by case basis before release into the environment. The Committee's initial view was that no organisms containing genes conferring resistance to antibiotics with applications in human therapy should be released into the food chain. However, it was apparent that there could be good scientific reasons to justify the use of such marker genes in certain situations. Furthermore there is a paucity of directly applicable data, and therefore a more detailed consideration of this question is to be undertaken in consultation with the Advisory Committee on Genetic Modification (ACGM) and ACRE. This will include reviewing information from related areas such as the spread of drug resistant bacteria, the potential for transfer of genetic material to gut microflora and the genetic stability of genetically modified organisms.

11. Labelling of Novel Foods

Whilst advice on the safety of novel foods is provided by ACNFP, advice on the labelling of such foods is within the remit of the FAC. Therefore, the Committees held a joint meeting to discuss common areas of interest in particular the labelling requirements for foods obtained from genetically modified sources. Guidelines on labelling have been prepared and made available as a part of a consultative exercise; details of these guidelines appear in both an FAC publication (4) and the ACNFP Guidelines (3).

12. Developments Elsewhere

The Committee is also kept up-to-date on any developments in the EC and in other countries on novel foods and processes and on irradiation.

In keeping with its remit the Committee assesses any new scientific information that becomes available on irradiation or on novel foods and processes.

13. Contact Points

Those wishing to seek further information about the general work of the Committee shoul in the first instance contact the Administrative Secretary, Ms C Brock, Department of Health, Room 609, Eileen House, 80-94 Newington Causeway, London SE1 6EF. Information about specific scientific points or concerning individual submissions (which have been made or are being contemplated) may be obtained by contacting the Scientific Secretary, Dr D Jonas, Ministry of Agriculture Fisheries and Food, Room 218 Ergon House, c/o Nobel House, 17 Smith Square, London SW1P 3JR.

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 Administrative Secretariat)
2. The Food (Control of Irradiation) Regulations 1990. Statutory Instrument No. 24 of 1990. HMSO. ISBN 0-11-005687-6
3. Department of Health. *Guidelines on the Assessment of Novel Foods and Processes* Report on Health and Social Subjects No.38. London, HMSO 1990. ISBN 0-11-321336
4. Ministry of Agriculture, Fisheries and Food. *Guidelines for the Labelling of Foods Produced Using Genetic Modification*. 1991. (Available from MAFF, FAC Secretariat, 504 Ergon House, c/o Nobel House , 17 Smith Square, London SW1P 3J

In line with the Committee's view on the public availability of data, the following have been deposited with the British Library:-

Sup. 11080 on Genetically modified bakers yeast.

Sup. 11083 on Fructose syrup.

For further details, please contact, Customer Services, British Library Document Supply Centre, Boston Spa, Wetherby, LS23 7BQ.

ANNEX I

PRESS RELEASE ON A GENETICALLY MODIFIED BAKERS YEAST

Joint Announcement by the Ministry of Agriculture, Fisheries and Food and the Department of Health

86/90 1 March 1990

CLEARANCE GIVEN TO NEW YEAST STRAIN

The Government has cleared for use by bakers a genetically manipulated yeast following scrutiny by the Advisory Committee on Novel Foods and Processes, and the Food Advisory Committee.

The organism is a strain of yeast which has had genes from a sister strain inserted to speed the production of certain enzymes responsible for dough fermentation.

The product has also been reviewed by the Advisory Committee on Genetic Manipulation and its Intentional Introductions Sub-Committee from the viewpoint of wider safety and environmental considerations. They have endorsed the conclusion of the ACNFP that the product may be used safely.

NOTES FOR 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 relevant expert bodies."

2. The Advisory Committee on Genetic Manipulation (ACGM) was established by the Health and Safety Commission under the Health and Safety at Work etc Act 1974. Its Chairman is Professor Sir Hans Kornberg FRS and membership is drawn from employers representatives, employees representatives and also includes medical and scientific specialists.

3. The Food Advisory Committee is a non-statutory body currently chaired by Dr Ewan Page, Vice-Chancellor of Reading University. Its main task is to advise Agriculture and Health Ministers on all matters relating to food composition, labelling and advertising.

4. Copies of the ACNFP advice on the yeast manufactured by Gist-Brocades are available from the Department of Health, Room 619, Eileen House, 80-94 Newington Causeway, London, SE1 6EF. This advice was also published in the last ACNFP annual report.

ANNEX II

PRESS RELEASE ON FRUCTOSE SYRUP

Joint Announcement by the Ministry of Agriculture, Fisheries and Food and the Department of Health

FSD65/90

6 September 1990

CLEARANCE GIVEN TO NEW FRUCTOSE SYRUP

The Government has cleared for food use a fructose syrup containing dextrans produced by Fisons Pharmaceuticals, following scrutiny of its safety by the Advisory Committee on Novel Foods and Processes.

The Advisory Committee was satisfied that there were no health or safety reasons why the use in food of this fructose syrup product as described by the company concerned should not be acceptable.

Fructose syrups are already in widespread use in the food industry. This particular fructose syrup is a by-product of the manufacture of dextrans for clinical use, and is obtained in a fermentation process that is in use throughout the world.

It is intended for use as a sweetener in speciality products such as diabetic and dietetic foods. The new syrup would be subject to the same labelling requirements as those already in use in food.

As part of the evaluation process the product has also been reviewed by the Committee on Toxicity.

- ends -

NOTES FOR 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.

2. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) advises the Government on the toxic risk to man of chemicals to which he is exposed from food, consumer products and the environment. It is chaired by Professor P Turner, Professor of Clinical Pharmacology, at St Bartholomew's Hospital Medical College.

3. Novel foods are defined in the Food Safety Act 1990 as "any food which has not previously been used for human consumption in Great Britain or has been used only to a very limited extent." The scope of the definition is necessarily broad and would encompass foods such as new strains of traditional food crops produced using techniques of genetic manipulation, or bacterial sources of proteins, fats or other food substances.

4. The fructose syrup containing dextrans is obtained in a fermentation process using a naturally occurring strain of the bacterium Leuconostoc mesenteroides.

5. The Committee on Toxicity advised that the dextrans present in the product would be metabolised in the gut at the likely intake levels.

6. Diabetic foods containing conventional fructose syrups and other bulk sweeteners must be labelled that it is best not to exceed an intake of 25g per day (because of possible laxation).

7. Copies of the ACNFP advice on the fructose syrup manufactured by Fisons Pharmaceuticals plc are available from the Department of Health, Room 619, Eileen House, 80-94 Newington Causeway, London SE1 6EF. This advice was also published in the first ACNFP annual report

ANNEX III

PRESS RELEASE AND ACNFP REPORT ON CHYMOSIN FROM TRANSGENIC *KLUYVEROMYCES LACTIS*.

FSD 4/91 17 January 1991

GOVERNMENT ACCEPTS ADVICE ON A NEW ENZYME PREPARATION

Food Minister David Maclean announced today that the Government had cleared for use in cheese manufacture a new enzyme preparation, derived from a genetically modified organism.

The decision follows advice from the Food Advisory Committee (FAC), which was acting on recommendations given by the Advisory Committee on Novel Foods and Processes (ACNFP) and the Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), that this enzyme preparation is suitable for use in food.

Responding to the FAC's advice, Mr Maclean said:-

"Following advice from the Food Advisory Committee (FAC) I have agreed to allow the use in cheese production of a new enzyme preparation derived from a genetically modified organism.

This preparation will provide a valuable new source of the enzyme chymosin, which occurs naturally in calf rennet and which is responsible for the coagulation of milk in the manufacture of cheese".

The organism involved is a yeast modified by addition of genetic material from calf cells. This allows the yeast to produce calf chymosin when it is grown under controlled conditions. The enzyme is then purified, and the preparation to be used in cheese-making contains none of the yeast cells.

Rennet has traditionally been obtained from the stomach lining of calves, but this source has proved to be unreliable and has not been able to keep up with increasing world demand, leading to shortages and higher prices for cheese manufacturers. This new

source of chymosin will help to assure a steady supply and a stable price.

Mr Maclean added:-

"This is one of a number of food additives being developed with the help of gene technology, which will be assessed for need and safety.

The FAC has also considered whether cheese made using the newly-derived enzyme should be specifically labelled and has concluded that since the enzyme is identical to the one found in calf rennet, special labelling is unnecessary.

The FAC has advised Ministers generally on the labelling of foods produced using genetic modification and I have published that advice separately today."

NOTE FOR EDITORS

1. The use of enzymes in the UK is currently controlled by the general provisions of the Food Acts which stipulate that nothing must be added to food which renders it injurious to health. There are also provisions in specific compositional regulations, such as the Cheese Regulations 1970, (as amended), which control the use of enzymes in particular foods.

2. The Food Advisory Committee is a non-statutory body comprising a chairman and 14 members all appointed for their personal expertise and experience and not representing any particular interests. Its terms of reference are as follows:

"To assess the risk to humans of chemicals which are used or occur in or on food and to advise Ministers on the exercise of powers in the Food Safety Act 1990 relating to the labelling, composition and chemical safety of food. in exercising its functions the food Advisory Committee will take the advice and work of the Committee on Toxicity and other relevant advisory committees into account."

3. A copy of the FAC's guidelines on the labelling of GMOs was issued today, press release number FSD 5/90.

4. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) is an independent body whose members are appointed by the Chief Medical Officer and advises the Government on the toxic risk to man of chemicals to which he is exposed from food, consumer products and the environment.

5. 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."

END

References

Unpublished reports submitted by Gist-Brocades, 1989.
(It is hoped to deposit these with the British Library in the near future).

Department of Health and Social Security
Eileen House 80-94 Newington Causeway London SE1 6EF
Telex Telephone

Your reference

Our reference

Date

25 October 1989

Dear

SUBMISSION FROM GIST BROCADES FOR A CHYMOSIN ENZYME DERIVED FROM A GENETICALLY MANIPULATED KLUYVEROMYCES LACTIS SOURCE ORGANISM

The FAC sought the advice of the ACNFP on the safety of chymosin derived from a genetically manipulated Kluyveromyces lactis source organism developed by Gist Brocades. The ACNFP has considered the data provided by the Company on:

- The genetic manipulation procedure used to obtain the source organism
- the fermentation method of production of the commercial enzyme preparation
- the characterisation of the chymosin thus obtained in comparison with the calf-derived enzyme

The ACNFP advice is that there are no particular safety concerns arising from the genetic manipulation procedure used to obtain this transgenic K lactis organism for use as a source for the enzyme chymosin. However the Committee does stress the importance of a well-defined process specification for the commercial enzyme preparation, including the relevant process control criteria, and the need to monitor the production strain for purity and stability.

Yours sincerely

EB/2764s+/1

ANNEX IV

ACNFP REPORT ON PASSION FRUIT SEED OIL

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

REPORT ON A SEED OIL FROM THE PASSION FRUIT

INTRODUCTION

In April 1990, the Committee was asked to examine the safety-in-food use of a seed oil from the passion fruit (Passiflora edulis) submitted by Anglia Oils Ltd. The oil is intended for use in speciality foods and salad dressings.

PROCESS DESCRIPTION

The oil is obtained by cracking and pressing the seeds of the passion fruit. Refining of the oil is by techniques used for more conventional food oils: neutralisation, bleaching and deodorisation according to good manufacturing practice.

USE

The oil has high linoleic acid and low saturated fatty acid contents and is seen to have potential in the speciality food/salad oil market. Possible market sectors include delicatessan and ethnic niche retail and mainstream retail as a part of speciality ranges.

SAFETY EVALUATION

In its assessment of the safety-in-use of the passion fruit seed oil, the Committee recognised that the seeds of the passion fruit are usually eaten with the fruit. It also noted that whilst unripe passion fruit may contain cyanogenic compounds, these are not found in the seeds (Spencer, K.C. and Siegler, D.S.; J. Agric. Food Chem.; 31 794-796 (1983)). Specifications of both the crude and the refined oils were considered, including data on fatty acid composition, the presence of natural oxidants and the content of cyanide, mycotoxins and heavy metals.

CONCLUSIONS

The Committee considered that, apart from its fatty acid spectrum, there was little to distinguish the oil from passion fruit seeds from oils obtained from other kernels. The Committee is satisfied that there are no food safety reasons why the use in food of the passion fruit seed oil should not be acceptable provided that it complies with the attached specification of purity.

Specification of passion fruit seed oil

Source: seeds of the passion fruit Passiflora edulis

Contaminant limits:

Lead	0.30 ppm	
Cadmium	0.20 ppm	
Mercury	0.02 ppm	
Arsenic	0.01 ppm	
Copper	1.00 ppm	
Maltols	10.00 ppm	(total)
Cyanide	20.00 ppm	
Aflatoxins	4.00 ppb	(total)

Fatty acids: typical values (%)

Lauric	C12:0	0
Myristic	C14:0	0
Palmitic	C16:0	9.0
Margaric	C17:0	0
Stearic	C18:0	2.0
Arichidic	C20:0	0.1
Palmitoleic	C16:1	0.3
Oleic	C18:1	13.5
Linoleic	C18:2	74.6
Linolenic	C18:3	0.5