Annual report : 1997 / Food Advisory Committee, Ministry of Agriculture, Fisheries and Food.

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FOREWORD

The Committee has carried out its work this year against a background of significant change. We have noted with concern the deterioration in public confidence on food safety issues arising from the BSE and *E.coli* crises. We therefore welcome the positive steps that are being taken to restore confidence by the establishment of the Food Standards Agency. Although much of the detail has yet to be worked out, it is the clear intention that the Agency will have wide ranging powers that will enable effective control of food safety to be maintained. The Agency will be able to draw on the wealth of expertise already available through committees such as the FAC. In the meantime, we welcome the special role that the Committee will have in providing advice to Ministers in the run up to its establishment, and the interest shown by Ministers in our work.

Transparency and openness will be essential to the successful operation of the Agency. Over the last year the FAC has taken a number of steps to make its work more accessible. Press Releases can now be accessed via the Internet, and minutes of meetings and committee papers are available on request. The first issue of our quarterly newsletter *Food for Thought* was published at the end of the year and has been well received by both industry and the public. In the future, I hope it will be possible for the Committee to hold conferences to discuss significant issues, and to open some meetings to the public and other interested parties.

I would like to thank my colleagues for their continued support and for the valuable contributions they have made during the year. I am also indebted to the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment and the Advisory Committee on Novel Foods and Processes for their assistance and expert advice on safety matters. Finally, I would like to place on record my appreciation of the high level of professional support provided by Dr Lawrie and his colleagues throughout the year.

Colin M. Campbell

PROFESSOR SIR COLIN CAMPBELL
Chairman

FAC COMMITTEE MEMBERS

(as at 1 November 1997)

Seated left to right: Professor Susan Shaw, Mr Roger Manley (Deputy Chairman), Professor Sir Colin Campbell (Chairman), Mrs Barbara Saunders, Mrs Dorothy Craig.

Standing left to right: Dr Maureen Edmondson, Dr Catherine Humphries, Professor Christopher Ritson, Mr Neville Craddock, Professor Alan Malcolm, Mr Philip Strachan, Mr Tom Miller, Professor Catherine Geissler, Mr Malvern Barnett.

Inset: Professor Frank Woods and Mrs Matti Alderson.

1. THE COMMITTEES' WORK IN 1997 - AN OVERVIEW

1.1 A large proportion of the Committee's time during the last year has again been spent looking at specific food safety issues where it has endeavoured to provide clear advice to Ministers on matters of concern such as levels of vitamin B6 in dietary supplements, chloropropanols in food and food ingredients and furfural. The Committee has continued its on-going work on food surveillance in commenting on the results of seven food surveys carried out by MAFF. It has also discussed the future programme of work in this area as well as the important issue of the criteria for releasing surveillance results. These, together with the Committee's consideration of various labelling issues, represent a substantial body of work, all aspects of which are reported in detail in the Report. In 1996 the Committee initiated two major reviews, on functional foods and health claims and on food intolerance and adverse reactions to food and food additives. The Committee has received regular reports on the progress of these reviews throughout the year. It is likely that the final reports will be considered by the FAC during 1998.

1.2 Perhaps the most significant area of change has been that of food safety. Soon after it came into office in May, the Government published a report by Professor Philip James of the Rowett Research Institute which set out detailed recommendations for the establishment of a Food Standards Agency (FSA). The Committee responded to this by making a number of suggestions which emphasised the importance of openness and clear explanation of food issues in ensuring the Agency's success. The Government's response to the James Report on the FSA was given in a White Paper issued in January 1998. Many detailed points need to be considered and it is unlikely that the Agency will be set up until the autumn 1999 at the earliest.

1.3 In the meantime Ministers have introduced a range of measures to strengthen food safety arrangements in the transitional period before the establishment of the Agency. As part of this, the remit of the FAC has been expanded to give it amongst other things, an over-arching role in the handling of food safety matters to enable it to cover any issues which do not fall naturally within the remit of any of the existing Committees.

1.4 The Committee's terms of reference have thus been expanded to embrace:

- Overall presentation of food safety machinery to the general public;
- General issues of risk assessment; and
- Any other questions which cut across different areas of food safety policy.

1.5 The setting up of the Food Standards Agency is clearly an issue that will need careful consideration and will require an input from a number of sources. The Government plans to consult the Committee at various stages in working out the details of the FSA.

1.6 The FAC traditionally holds one of its meetings away from London, combining the event with a visit to a food-linked establishment in order to gather, at first hand, background information on current topics under discussion. This year the Committee visited the Unilever Research Centre at Colworth near Bedford where it was given a presentation on toxicological risk assessment and had a tour of the Centre's analytical facilities for determining levels of chloropropanols and mycotoxins in food products, which were under consideration by the Committee during 1997.

2. ADDITIVES AND OTHER SUBSTANCES USED IN OR OCCURRING IN FOOD

Levels of vitamin B6 in dietary supplements

2.1 The Committee's 1996 Annual Report provided the background to its consideration of this issue, which followed advice from the COT that the daily intake of vitamin B6 should not exceed 10 mg per day.

2.2 The Committee returned to this issue in June when it considered the response of interested parties to its earlier recommendation that the advice of the COT be implemented as soon as possible. It took note also of a further statement issued by the COT, following its consideration of additional information on vitamin B6 provided by industry, complementary medicine and consumer interests which endorsed its earlier recommendation. In addition, the Committee considered the results of a MAFF survey of the vitamin B6 content of dietary supplements and was informed of the outcome of a review of vitamin B6 in licensed medicinal products by the Committee on the Safety of Medicines (CSM).

2.3 Having considered the COT's further advice, the Committee endorsed the recommendation that dietary supplements should not provide a daily dose of more than 10 mg. It also recommended that all dietary supplements containing vitamin B6 should carry a warning label about the possible harmful effects of intakes above 10 mg of this vitamin per day. The Committee also considered that, if necessary, these requirements should be the subject of legislation.

2.4 Ministers accepted the FAC's advice and instructed officials to draw up appropriate legislation under the Food Safety Act 1990.

Review of vitamins and minerals in dietary supplements

2.5 In the UK, vitamins and minerals which are not licensed as medicines are treated as foods and are therefore regulated under the Food Safety Act 1990. A safety-based approach is used, whereby there are no specific restrictions on the sale of vitamins and minerals provided there is no evidence of risk to health. Therefore, maximum levels of vitamins and minerals in dietary supplements have been defined in only a few cases. However, the Government believes that there is a general need to review the safety of vitamins and minerals sold as supplements and has asked the advisory committees to undertake this as quickly as possible.

2.6 As a first step, officials sought the views of expert committees including the FAC on a proposal to establish an *ad hoc* Expert Group drawn from representatives from the COT, the Committee on the Medical Aspects of Food and Nutrition Policy (COMA), the CSM and the FAC. Observers from interested parties and other member

states would also be invited to the Expert Group's meetings. Its remit would be to consider toxicological, nutritional and medical aspects of vitamins and minerals and would report to the CSM (which regulates medicinal products) and the FAC (which advises on other products) within 18-24 months.

2.7 At its October meeting, the Committee endorsed the proposed way forward and gave its advice on the terms of reference of the Expert Group. Following receipt of this and the advice of the other relevant advisory committees, Ministers agreed to the establishment of the Expert Group.

Canthaxanthin

2.8 Canthaxanthin is an orange-red pigment currently permitted for use in animal feeds, primarily to colour egg yolks and the flesh of farmed salmon and trout. In March 1990, on the basis of safety advice from the COT, the Committee recommended that the pigment should no longer be used in animal feed. Although Ministers accepted this advice and the UK sought a ban on its use in Europe, the EC Scientific Committee for Animal Nutrition (SCAN) did not consider that an immediate ban was necessary. After consulting the EC Scientific Committee for Food (SCF), SCAN advised that the situation should be reviewed once further data were available. In June, following a review of these further data by the SCF, an Acceptable Daily Intake (ADI) of 0-0.03 mg/kg body weight was set.

2.9 At its September meeting, the Committee considered estimates of the potential intake of canthaxanthin by UK consumers. The Committee noted that intakes were generally well below the ADI. However, it was concerned that the consumption data for infants were now more than 10 years old and may not fully reflect current food consumption patterns; for example farmed fish is now more readily available than it was at the time of the survey. The Committee therefore requested further information on potential intakes of canthaxanthin by young children before reaching a final decision on this issue.

Furfural

2.10 Furfural is a chemically defined flavouring substance which is used as a constituent of flavouring blends in a wide range of savoury foods, bakery goods, confectionery and dairy products, and in alcoholic and non-alcoholic beverages.

2.11 As reported in the 1996 Annual Report, furfural first came to the attention of the Committee in December 1996, following advice from the SCF that it should not be used as a flavouring substance due to evidence of carcinogenicity and genotoxicity. At that time, the Committee recommended that industry should be encouraged to find alternatives to the use of this substance. It also recommended that MAFF should press

the European Commission to act on the SCF's advice and prohibit its use as soon as possible.

2.12 The Committee was given an update on the latest position on this issue at its September meeting. It was informed that the Commission had decided not to introduce a Community-wide ban on furfural at the present time. However, it did intend to exclude it from the EU-wide register of flavouring substances which was currently being drawn up and which would eventually lead to a positive list of flavourings. The Commission had also indicated that it would be unlikely to take action against any member state which banned the use of furfural in its territory before 2004 when the list was expected to take effect, even though such a ban could be regarded as a barrier to trade.

2.13 The Committee was encouraged by information which showed that many companies had already taken steps to ensure that furfural was being phased out in the UK, and expressed a wish that this trend should continue. The Committee was also informed that the US Flavor and Extract Manufacturers' Association was able to provide details of new toxicity studies which it claimed would show that furfural was safe and recommended that these be passed to the SCF for evaluation. However, the Committee did not consider that there was any reason to alter its advice at this stage.

Hemicellulase enzymes used in breadmaking

2.14 To date, the Committee has considered and given full approval to six hemicellulase enzyme preparations for use in breadmaking. In July 1997, the COT recommended the approval of a further preparation derived from a genetically modified strain of *Aspergillus niger* (Pentopan Mono - manufactured by Novo Nordisk). Because the preparation was derived from a GM source, advice from the ACNFP was also sought . The ACNFP had no concerns about the genetic modification aspects of the submission and approved the use of the preparation at its April 1997 meeting. The company subsequently provided COT with the necessary information for it to complete its toxicity evaluation and full approval for its use was given in July.

2.15 In the light of the information provided by the two Committees, the FAC was also able to give its full approval to this preparation at its September meeting. The Committee also decided that in line with existing arrangements for other enzymes used in bread, there was no need for a labelling requirement to indicate its use.

Phthalates in infant formulae

2.16 As reported in the 1996 Annual Report, during 1996, the Committee had been informed of the results of a limited survey of phthalates in infant formulae and of the advice of the COT that the levels found were unlikely to pose any health risks. In line with the COT's advice, the Committee had agreed that it would be prudent to ensure

that adequate safety margins were maintained. The Committee had welcomed the steps that manufacturers had already taken to trace the source of phthalates in food so that levels could be reduced, and had agreed that this matter should be kept under review.

2.17 In the course of 1997, officials continued to meet regularly with representatives from the infant formulae manufacturers and their trade association the Infant and Dietetic Foods Association (IDFA) to discuss their continuing work on phthalates.

2.18 At the Committee's December meeting, the industry's progress in carrying out these investigations was discussed. The Committee noted that current levels of phthalates in infant formulae were reported to be considerably lower than in 1996 but that it was not clear whether this was due to an improvement in the analytical methods used or to a genuine reduction in the levels of contamination. The Committee asked for a further report in the spring of 1998, when it is expected that the results of a MAFF survey will be available.

Chloropropanols in food and food ingredients

2.19 The 1996 Annual Report provided the background to the Committee's advice of October 1996 on the contaminant 3-monochloropropane-1,2-diol (3- MCPD), which is considered by the SCF to be a potential human carcinogen. At that time, the Committee had recommended that within 18 months industry should take the necessary action to ensure that 3-MCPD could not be detected in foods or food ingredients using a method capable of measuring this contaminant down to levels of 0.01 mg/kg.

2.20 At its December meeting, the Committee was given a progress report on the action taken by the industry to comply with its advice. As part of this, it considered action plans drawn up by different sectors of the food industry. It expressed concern that an action plan proposed by the meat sector did not appear as well advanced as those from the cereals or dairy sectors and urged that sector to provide officials with a more detailed plan of how it intended to tackle this issue. The Committee agreed that the situation should be reviewed again in spring 1998, by which time industry should have identified any problem areas.

2.21 It was also reported that progress had been made to validate an analytical method capable of detecting 3-MCPD in a wide range of foods and food ingredients down to a level of 0.01 mg/kg. The Committee was informed that this work was likely to be completed by March 1998 and that it was intended that a fully validated method would be widely available shortly afterwards.

2.22 The Committee also noted preliminary data which appeared to indicate the potential for 3-MCPD to migrate into food from some types of packaging material and asked to return to this issue once the situation had been investigated in more detail.

EC Regulation on ochratoxin A in food

2.23 Ochratoxin A (OA) is a naturally occurring mycotoxin produced by some fungal species of the *Aspergillus* or *Penicillium* genera. It is considered to be a genotoxic carcinogen by the COT. In 1994, the European Commission brought forward a working document for a proposal on mycotoxin contamination of food which included limits for aflatoxins, OA and patulin. In order to simplify the discussions each substance was to be the subject of a separate proposal. Progress has been made on aflatoxins, but proposals on patulin and OA are awaiting reassessments of safety advice by the SCF.

2.24 At its October meeting, the Committee discussed a possible EC proposal for the regulation of OA in food. Whilst the Committee was not opposed to the regulation of OA in the final product, it considered that controls based on Hazard Analysis of Critical Control Points (HACCP) would be the most effective way of minimising exposure to this contaminant. Officials were requested to take account of the Committee's views when formulating the UK response to future EC proposals.

3. LABELLING AND INFORMATION

Labelling of Genetically Modified (GM) Products

3.1 In February advice was sought from the Committee on the labelling of two genetically-modified (GM) products. In both cases the Advisory Committee on Novel Foods and Processes (ACNFP) had already approved the products on safety grounds. The products, both of which were considered by the Committee in February, were:

- Oil from a genetically modified glufosinate-tolerant oilseed rape;

- Processed products derived from a genetically modified insect-resistant maize line.

3.2 In both cases the Committee considered that there was no need for any special labelling as a condition of approval as it considered that the final products were indistinguishable from those derived from conventional sources. However, the Committee continued to encourage the provision of information on GM foods and food ingredients, including labelling, on a voluntary basis in response to consumer interest. The Committee recognised that these products would become subject to the labelling provisions of the forthcoming EC Novel Foods Regulation by the time they came on the market.

3.3 The Committee's advice and that of the ACNFP was accepted by the then Government.

EC Novel Foods Regulation

3.4 At its meeting in March, the Committee compared its previous advice on the labelling of GM foods with the terms of EC Regulation 258/97/EC on Novel foods, which came into force on 15 May 1997 and sets out special labelling requirements for novel foods.

3.5 The Committee was satisfied that its previous advice was consistent with the criteria set out in the new EC Regulation, and agreed with the European Community's intention to consider labelling requirements for future novel foods, including those from GM sources, on a case by case basis. The Committee also confirmed that companies should continue to be encouraged to provide additional information to consumers on a voluntary basis and as a matter of routine.

Quantitative Ingredient Declaration (QUID)

3.6 As a result of EU legislation adopted in January, most food products will, by February 2000, have to declare the quantity of any ingredients which:

- Appear in the name of a food or which are usually associated with that name by consumers;

- Are emphasised on the label in either words, pictures or graphics; or

- Are essential to characterise the food and to distinguish it from products with which it might be confused because of its name or appearance.

Declarations must appear in or next to the name of the food, or in the ingredients list, and must be shown as a percentage (based on the amount of the ingredient used at the manufacturing stage).

3.7 In August, MAFF issued draft Guidance Notes which were circulated to interested parties for comment. These notes are intended to assist manufacturers and enforcement authorities to interpret the legislation and they were considered by the Committee in September. Officials were asked to take account of members' comments, along with any others received, at the end of the consultation period. The Committee also invited officials to refer back any major points which emerged from the consultation for further consideration and advice.

4. FOOD SURVEILLANCE

Procedures for the release of surveillance results

4.1 The 1996 Annual Report gave details of several proposed changes to the existing system of reporting surveillance results. The Committee had noted that MAFF was consulting interested parties on these generally and on the question of releasing results for individual named samples in particular.

4.2 At its March meeting, the Committee discussed the issue of brand names. The Committee emphasised that surveillance exercises should not become a substitute for enforcement action; the two served entirely different purposes. It also advised that, where a problem was identified in relation to a particular product, the manufacturer/retailer involved should be given adequate opportunity to respond to the findings.

4.3 Arrangements for consulting the Committee by post in cases where there was insufficient time for the information to be presented at a meeting before publication were also discussed. These were slightly amended in line with members' comments following the first survey cleared by this procedure.

Irradiation of foodstuffs

4.4 At its March meeting, the Committee considered the results of a survey, carried out by the Working Party on Food Authenticity (WPFA), which investigated whether undeclared irradiated herbs and spices, chicken, shrimps and prawns, fruit and vegetables and liquid egg were being sold through retail outlets and to the catering industry in the UK.

4.5 The Committee noted that 99.5% of the foods in the survey (785 out of 789) had not been irradiated and were therefore correctly labelled. In regard to four spice samples found to be irradiated or to contain irradiated components without being labelled as such, the Committee encouraged the close involvement of the relevant Local Authority Trading Standards Departments to enable appropriate follow-up action to be taken.

Survey of iodine and other nutrients in milk

4.6 Iodine is an important nutrient and is required for the synthesis of thyroid hormones. Inadequate intake can lead to iodine deficiency diseases whilst high intakes can result in functional impairment of, and tissue damage in, the thyroid gland. It is

therefore important that intakes and sources of iodine are monitored on a regular basis. This is done as part of a programme of nutrient analyses and dietary surveys.

4.7 At its September meeting, the FAC considered the results of a survey of the nutritional value of pasteurised milk recently carried out by the Working Party on Nutrients in Food. The Committee was asked to pay particular attention to the results for iodine (milk is an important source of iodine in the UK diet) and to consider a statement from the COT on the possible risks to health of high levels of iodine.

4.8 The majority of results were in the range expected and gave no cause for concern. However, some increases in iodine levels had been found compared to earlier surveys. The Committee noted that the intake of iodine, expressed in terms of body weight, may exceed maximum guideline levels in some young children. However, it was reassured by the COT's advice that this was unlikely to pose a risk to health and did not therefore consider that there was any need to limit consumption in young children on safety grounds. Nevertheless, the Committee considered that a further study to determine iodine levels in milk should be commissioned at the earliest opportunity and recommended that this should include an investigation of the chemical form in which the iodine is present.

Added water in cured pork products

4.9 The WPFA had carried out an investigation into whether cured pork products being sold through retail outlets in the UK were misdescribed with respect to the amount of added water. Samples were obtained from a range of large, small and discount supermarkets, butchers shops and other small retailers.

4.10 The results of the survey were considered at the Committee's September and October meetings. The Committee concluded that, because of the methodology used, the interpretation of the analytical data was appropriate for this surveillance exercise but not for enforcement purposes. It noted that the survey had shown that the percentage of samples that was incorrectly labelled as to their water content was low (less than 3%), although there were differences in the level of misdescription between raw and cooked samples and between large and small outlets. The Committee was aware that the addition of water to meat remained an issue of concern to consumers and encouraged enforcement authorities to continue monitoring the situation and to ensure that defaulting companies took appropriate remedial action.

Nitrate and nitrite in bacon and cured meat products

4.11 At its December meeting, the Committee considered the results of a MAFF survey of levels of nitrate and nitrite in bacon and cured meat products. These substances have a long history of use as preservatives and can be an important means of ensuring the safety of cured meats. The Committee noted the main conclusion from

the survey; that total levels of nitrate and nitrite in cured meats were comparable with those obtained in the previous survey which was carried out in 1989. Whilst welcoming the reassuring results obtained from the survey, the Committee stressed the need for manufacturers to ensure that their products contain adequate amounts of preservatives to ensure microbiological safety.

Ochratoxin A in dried vine fruits

4.12 In a postal consultation in October, the FAC was asked to comment on the outcome of a survey of OA and aflatoxins in cereals and a variety of retail products, including dried vine fruits (raisins, currants and sultanas). The results although generally reassuring, revealed unexpectedly high contamination of dried vine fruits by OA. The COT had been asked for its views on the implications for public health of the concentrations that had been found. In its statement, the COT had advised that although consumers would be unlikely to suffer any adverse effects as a result of this contamination, it would be prudent to reduce the levels of OA contamination to the lowest level technologically achievable.

4.13 In its statement, the FAC endorsed the COT's recommendations and advised that industry should take immediate action to identify the causes of the problem and rectify them. Furthermore, it asked to see the results of a more extensive survey of dried vine fruits to check that future levels of OA were substantially reduced. The Committee also recommended that dried vine fruit be included in the list of commodities being considered in forthcoming EC legislation, setting limits for OA in food (see paragraphs 3.23 - 3.24)

Whisky substitution in the on-trade

4.14 Whisky sold in on-trade outlets (pubs, clubs, hotels, restaurants, etc) must be dispensed either from an optic or by using a measuring thimble. As the seal on the bottle is not usually broken in front of the customer, the potential exists for the contents, to be entirely or partly substituted with a different brand, or to be diluted.

4.15 In October, the Committee considered the results of a survey carried out on behalf of the WPFA which examined 161 samples of the five best-selling brands of whisky purchased in various outlets around the UK for substitution with another brand, or for dilution.

4.16 The Committee was reassured that the overwhelming majority of the samples examined were of the brand requested and at the correct alcoholic strength. However, it noted that approximately 4% of whiskies were either not the brand or the strength declared on the label and was pleased that these results had been brought to the attention of the relevant enforcement authorities.

Dioxins and polychlorinated biphenyls (PCBs)

4.17 In May, the Chief Medical Officer announced the completion of a review by the COT of the health hazards of polychlorinated biphenyls (PCBs). As part of its review, the COT considered data on PCBs and dioxins in food, human milk and fish oil dietary supplements. The COT recommended a Tolerable Daily Intake (TDI) for dioxins and PCBs; the most recent estimates of UK dietary intakes of these chemicals show that average intakes are well below the TDI and have fallen substantially over the decade 1982-92. Although estimated intakes of dioxins and PCBs by breast-feeding babies are higher than is desirable, the COT re-affirmed its previous advice that breast-feeding should continue to be encouraged on the basis of convincing evidence of the benefits of human milk to the overall health and development of the infant. The COT also concluded that the estimated intakes of dioxins and PCBs from fish oil products are unlikely to pose a risk to the health of breast-fed infants, toddlers, schoolchildren or adults. However, consumption of some products could potentially lead to the TDI for dioxins and PCBs being exceeded by toddlers and schoolchildren, which is undesirable. Officials from MAFF, DH and the Medicines Control Agency subsequently met with representatives of the fish oil industry and discussed ways in which the concentrations of dioxins and PCBs in dietary supplements and medicinal products containing fish oils, and/or intakes of these chemicals from such products, can be reduced.

4.18 At its June meeting, the Committee endorsed the COT's advice that monitoring of PCBs and dioxins should continue. As part of the continuing programme of surveillance of food for the presence of PCBs and dioxins, three further surveys of cows' milk from farms close to industrial sites had been completed. In all cases, the concentration of dioxins and PCBs were lower than those found in the previous year and the results did not therefore give any cause for concern.

5. OTHER MATTERS

Better regulation

5.1 In June, the Committee considered a discussion paper on the review of the Meat Products and Spreadable Fish Products Regulations 1984. The review was initiated with the twin objectives of achieving better regulation whilst also up-dating the regulations in line with new EC requirements on QUID (see paragraph 3.6-3.7).

5.2 In discussing the paper, the Committee highlighted the legal definition of "meat" as a major issue that required careful consideration. However, it recognised that further progress was dependent on how the UK proposed to implement the EU labelling rules on QUID. The Committee agreed to return to this review in more detail at a future meeting once it had taken stock of developments on QUID.

Procedures for funding food research

5.3 At its December meeting, the Committee considered a paper which summarised the current system for funding food research in MAFF and which addressed a number of issues that members had raised earlier including:

- The arrangements for obtaining an external input into priority setting or the allocation of funds between different categories of research;

- The relationship between strategic research objectives and the policy issues which they seek to address;

- The ability to commission urgent work in response to any crisis which may occur and to carry out "speculative" work to identify problem areas; and

- The need for further research into consumers' attitudes towards food safety.

5.4 The Committee expressed a wish to be involved in the setting of priorities for MAFF-funded research in the run up to the establishment of the Food Standards Agency. It agreed to return to the question of research into public attitudes to food safety at a future meeting.

European Commission's Green Paper on the general principles of food law in the European Union

5.5 In April 1997, the European Commission circulated a Green Paper assessing the extent to which current EU food legislation meet the needs and expectations of

consumers, producers, manufacturers and traders; how well the official control and inspection systems are operating; and how food law can be developed in future. The issues raised in the paper were wide ranging and encompassed the protection of public health, the internal market, the CAP and the requirements of WTO agreements. As well as reaffirming the fundamental objectives of food law, the Commission stressed the need for a regulatory approach to cover all potential risks to the safety and wholesomeness of food at all stages of the food chain.

5.6 The Green Paper was not addressed to member states' governments but generally to all interested parties and individuals. Although widely circulated by MAFF, it was not the subject of a formal consultation.

5.7 At its September meeting, the Committee was asked to comment on a draft UK Government response. The Committee expressed its broad support for the comments made in the response and its views were passed to Ministers, who subsequently replied to the European Commission on behalf of the UK government.

TERMS OF REFERENCE, MEMBERSHIP AND SCOPE

1. The Food Advisory Committee (FAC) is an independent non-statutory body appointed by Ministers and has the following terms of reference:

"To assess the risk to humans of chemicals which are used 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. The Committee will also advise Ministers on general matters relating to food safety. In exercising its functions the Food Advisory Committee will take the advice and work of the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), the Advisory Committee on Novel Foods and Processes (ACNFP), the Advisory Committee on the Microbiological Safety of Food (ACMSF) and other relevant advisory committees into account."

2. The Committee's main task is to review and prepare reports on all matters within its terms of reference and where necessary to make recommendations for legislation. The Committee gives its advice to Ministers who may then decide to make that advice public. Its role and its relationship with other committees are described in more detail at **ANNEX II.**

3. A list of members of the Committee is at **ANNEX III**. During the year, one member, Mrs Joy Hardinge, left the Committee on expiry of her term of appointment and was replaced by Dr Maureen Edmondson. A new lay member, Mrs Matti Alderson was also appointed to the Committee.

4. Members are appointed to the FAC because of the expertise they have acquired through their professional involvement with the food industry or food issues generally. Committee members are required to declare any interest in matters to be discussed. The Chairman may then, at his discretion, limit the participation of a member in a discussion. The Committee and Ministers consider it important that the Committee's advice should not be subject to suspicion of bias on the grounds of undeclared commercial interests. A formal register of members' interests has therefore been established and is published at **ANNEX IV** of this Report. The Code of Conduct which is sent to all members on appointment is at **ANNEX V**.

THE ROLE OF THE FOOD ADVISORY COMMITTEE AND ITS RELATIONSHIP WITH OTHER COMMITTEES

THE ROLE OF THE COMMITTEE

Assessment of food additives

1. With the adoption of specific European Parliament and Council Directives on food additives and their implementation in the UK in 1996, the procedure for the assessment of additives has altered. Final approval of the use of a new additive is now subject to agreement at Community level, although there is a provision in the Food Additives Framework Directive (89/107/EEC), to enable a member state to authorise the use of a new additive within its own territory on a temporary basis. If a manufacturer requests that a new additive be permitted for use or that a new use be allowed for an additive already permitted, the manufacturer is encouraged to submit an application for its approval to the European Commission for it to be assessed by the SCF. At the same time, an application may be submitted to the FAC to consider whether there is a genuine need for that additive or use. With the benefit of safety advice from the COT, the FAC formulates advice to Ministers who then decide whether to grant temporary national authorisation. At the end of a two-year period, the additive may only continue to be permitted if a suitable amendment to the appropriate Directive has been agreed to by the Council of Ministers and the European Parliament.

Risk assessment

2. Risk assessment is a means of estimating potential harm. Any additive or other substance intentionally added to food is subject to risk assessment prior to approval and those already approved are reconsidered when new data is obtained, or if there are changes in intake levels (see paragraphs 3 and 5). Chemical contaminants can come from a variety of sources eg natural toxicants such as mycotoxins; soil and air contaminants such as metals; with the use of permitted additives or contamination arising from the use of food contact materials, and may therefore be more difficult to quantify than substances added intentionally. The Committee obtains advice on toxic risk to humans primarily from the COT or the SCF but also considers advice from other advisory Committees from time to time as well. Information on dietary intakes is provided from the MAFF database.

3. For substances other than genotoxic carcinogens, toxicological advice is usually provided in the form of an acceptable or tolerable daily intake (ADI/TDI) (paragraph 4). If dietary intakes of a particular substance in the human diet are likely to increase because of new uses or changing dietary patterns so that there is a possibility of

acceptable levels being exceeded, the Committee will then advise on the management of that risk. It might, for example, recommend maximum levels of use for a substance or that its use should be restricted or prohibited. Chemical contaminants found in food may be judged by the same criteria as additives, although there is usually less detailed information on their toxicity. The estimation of exposure may also present a greater practical challange, since the presence of contaminants may be subject to greater variation due to a range of factors. For example, levels of natural toxicants can be greatly influenced by conditions experienced during the growth of the crop and its subsequent storage. Risk management thus becomes a more complex task and a regular system of monitoring is essential. When new data concerning a currently approved additive or a known contaminant become available, the Committee may modify its previous risk management advice.

4. In recent years, the Committee's role in the risk assessment and risk management procedure has grown, largely as a consequence of the change in format of the safety advice offered by the COT. In the case of additives, the COT used to provide its advice in the form of broad categorisations, which defined the degree of suitability of a food additive for use in food. The COT, in line with most expert advisory committees on food safety, now issues its advice in a numerical form as an ADI. (When the estimated consumption of an additive is expected to be well below any numerical value that would ordinarily be assigned to it, an ADI 'not specified' may be allocated). The ADI has most recently been defined by the World Health Organisation (WHO) as 'an estimate of the amount of a food additive, expressed on a bodyweight basis, that can be ingested daily over a lifetime without appreciable health risk'. This change has meant that the FAC has become responsible for the final stage of the safety evaluation, as advice in the form of an ADI needs to be considered in the context of current and likely future intakes of the additive concerned. This is necessary in order to determine whether action is needed to maintain intakes by UK consumers within acceptable limits. In the case of contaminants, the COT's advice is in the form of a Tolerable Daily Intake (TDI) or a Tolerable Weekly Intake (TWI). For contaminants which are genotoxic carcinogens, the COT has advised that it is not possible to set tolerable intake levels. In this case, the COT advises that the levels of the contaminant in the food should be as low as is technically achievable. The FAC advises on what the level should be, balancing the need to keep levels as low as possible without unreasonably restricting the availability of food in terms of its supply or its cost.

Risk management

5. Where a potential risk to consumers is identified, the FAC balances this risk against evidence of possible benefit to consumers from the use of the substance or consumption of the relevant foods. This allows the FAC to recommend strategies for the effective management of food chemical risks. In order to maintain intakes within acceptable levels, current and future uses of additives may need to be restricted. Similarly, the presence of chemical contaminants in a food may require either physical

or chemical removal of the contaminant or the introduction of controls on the level permitted. In other cases, it may be more appropriate to issue advice to specific groups of the population who might be at potential risk of exceeding acceptable intakes.

Labelling

6. Food labelling is controlled by the Food Safety Act 1990 and the Food Labelling Regulations 1996 which implement the EC Food Labelling Directive 79/112/EC. This Directive largely harmonises food labelling legislation throughout the EU and there is now very little scope for national measures except for foods which are sold loose or in catering establishments. The Committee advises Ministers on labelling issues within this context, on new EU proposals, and on the need for special labelling for certain categories and individual products where this is permitted by the Directive. The FAC's 1990 Review of Food Labelling and Advertising set out the Committee's broad philosophy in this area and stressed the importance of clear, accurate and informative labelling.

The European aspect

7. A further and increasingly important aspect of the Committee's role relates to the harmonisation of legislation on matters of food safety, labelling and consumer protection throughout the EU. The FAC is one element of a wide process of consultation and advice to Ministers which helps form the basis for a negotiating position in Brussels. A number of detailed measures still remain to be agreed following the establishment of the Single European Market and it is important that the UK continues to play a significant role in the formulation of EU legislation.

THE FOOD ADVISORY COMMITTEE'S RELATIONSHIP WITH OTHER GOVERNMENT ADVISORY COMMITTEES

8. The FAC was formed in November 1983, following the amalgamation of the Food Additives and Contaminants Committee and the Food Standards Committee. It forms part of a network of committees that advises Government on many different aspects of food. The maintenance of close links between these committees is vital to the Government's role in ensuring the continued safety of our food supply. The following paragraphs explain the FAC's relationship with some of these other committees.

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)

9. The FAC works very closely with the COT (see paragraph 2-4 of this **ANNEX**), which is based in the DH. Members are appointed by the Government's Chief Medical Officer (CMO). Part of the COT's remit is to assess and advise on the toxic risk to humans of a wide range of substances affecting everyday life. This may include evaluation of data on substances used or proposed to be used as food additives, or substances which might contaminate food through their use or natural occurrence at any stage in the food production process, and to advise on their safety. The FAC takes full account of this advice in formulating its subsequent recommendations to Ministers. The FAC, in its role of risk assessment and risk management, therefore has to consider safety advice in the context of actual and likely future intakes of the substance by UK consumers, in order to advise Ministers of any restrictions on food use which might be required. Professor Frank Woods, Chairman of the COT and a member of the ACNFP, is also a member of the FAC.

Advisory Committee on Novel Foods and Processes (ACNFP)

10. The ACNFP is appointed to advise Health and Agriculture Ministers on matters relating to the manufacture of novel foods or foods produced by novel processes. The FAC, COT and the ACNFP work closely together at all times, such co-operation being illustrated by the way in which they continue to liaise over their considerations of different aspects of the application of GM technology to food production.

Committee on Medical Aspects of Food and Nutrition Policy (COMA)

11. COMA is a committee of experts chaired by the CMO. It provides the Government with independent advice on matters relating to nutrition, diet and health. Although COMA meets only twice a year, it operates through a system of sub-committees and expert panels set up to report to COMA on particular matters. Each sub-committee is chaired by a member of COMA. The FAC seeks the advice of COMA on specific nutritional matters.

Advisory Committee on the Microbiological Safety of Food (ACMSF)

12. The ACMSF advises Health and Agriculture Ministers on the risk to humans of micro-organisms which are used or occur in or on food and on matters relating to the microbiological safety of food. Mrs Barbara Saunders, a member of the FAC, is also a member of the ACMSF until the end of the year.

ANNEX III

LIST OF FAC MEMBERS

Members of the Committee are appointed for their personal expertise and do not represent particular interests. In general, they are drawn from areas of academia, the food industry, food law enforcement and consumer affairs.

FAC MEMBERSHIP DURING 1997

Professor Sir Colin Campbell (Chairman) DL LLB FRSA CIM	Vice-Chancellor, University of Nottingham
Roger Manley (Deputy Chairman) OBE FITSA	County Fair Trading and Advice Officer, Cheshire County Council
Matti Alderson BA FRSA FCAM (From 1 November)	Director-General, Advertising Standards Authority
Malvern Barnett MChemA CChem FRSC FIFST	Public Analyst and a partner in the analytical consultancy practice, Central Scientific Laboratories
Neville Craddock MA (Cantab)	Group Regulatory and Environmental Affairs Manager, Nestlé UK Ltd
Dorothy Craig MBE JP BSc	Member of the Executive Committee of the National Federation of Consumer Groups
Maureen Edmondson BSc PhD (From 1 November)	International Scientific Affairs Mars Incorporated
Professor Catherine Geissler BDS MS PhD	Professor of Nutrition, Department of Nutrition and Dietetics and Head of Division of Health Science, King's College, University of London
Joy Hardinge OBE BSc FIFST (Until 31 October)	Head of Legislation (Flavours and Ingredients), Quest International
Catherine Humphries PhD CChem FRSC FIFST	Chief Scientific Adviser, Co-operative Wholesale Society Corporate Affairs
Professor Alan Malcolm MA DPhil FIBiol FIFST	Director of the Institute of Food Research

Tom Miller BSc FIFST FRSH FHCIMA	Director of Food Regulatory Affairs, Whitbread plc
Professor Christopher Ritson BA (Econ) MAgrSc	Professor of Agricultural Marketing and Dean of the Faculty of Agriculture and Biological Sciences, University of Newcastle-upon-Tyne
Barbara Saunders BA	Freelance consultant on consumer policy
Professor Susan Shaw MA (Cantab) FCIM	Deputy Principal and Professor of Marketing, University of Strathclyde
Philip Strachan MA (Cantab) FIFST	Food Industry Consultant
Professor Frank Woods BSc BM BCh DPhil FIFST Hon FFOM FRCP (Lond and Edin)	Dean of the Faculty of Medicine, University of Sheffield

Officials of the Food Advisory Committee Secretariat

Secretary:	Sandy Lawrie BSc PhD
MAFF Assessor:	Jon Bell BSc PhD CChem FRSC
Department of Health Assessor:	Andrew Wadge BSc PhD CBiol MIBiol
Secretariat:	Ann Davies BSc MSc PhD DIC Dionne Davey Marian Laklia Keith Butler

FOOD ADVISORY COMMITTEE - REGISTER OF MEMBERS' INTERESTS

Members have declared current personal and non-personal interests as follows (as at 31 December 1997):

	PERSONAL INTERESTS (i.e. those involving payment to the member personally)		NON-PERSONAL INTERESTS	
MEMBER	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST
Prof. Sir Colin Campbell (Chairman)	None		Wide range of national and international food companies	Vice-Chancellor of the University of Nottingham some of whose research activities in food science and technology are supported by the food industry
Mr R Manley (Deputy Chairman)	None		None	
Mrs M Alderson (Appointed to the FAC 1 November 1997)	None		None	
Mr M Barnett	None		None	
Mr N Craddock	Néstle UK Ltd	Salary	None	
Mrs D Craig	None		None	
Dr M Edmondson (Appointed to the FAC 1 November 1997)	Mars Inc.	Salary	None	
Prof. C Geissler	None		Range of national and international food and pharmaceutical companies	Head of Division of Health Sciences, King's College, University of London, some of whose research activities in nutrition and pharmacy are funded by the food and pharmaceutical industry
Mrs J Hardinge (Retired from FAC 31 October 1997)	Unilever plc Quest International	Shareholder Salary	None	
Dr C Humphries	CWS Ltd	Salary	None	
Prof. A Malcolm	None		Wide range of national and international food companies	Director of the Institute of Food Research, the principal public-funded food research institute. Its departments also undertake confidential research contracts for food companies and Government or EC sponsored collaborative contract research, involving national and international food companies on topics of food composition, quality, safety, dietary effects, and new technology. Industry-funded studentship and research training fellowships are also received by the Institute.

MEMBER	PERSONAL INTERESTS (i.e. those involving payment to the member personally) NAME OF COMPANY	NATURE OF INTEREST	NON-PERSONAL INTERESTS NAME OF COMPANY	NATURE OF INTEREST
Mr T W Miller	Whitbread plc	Salary Shares and share option	None	
Prof. C Ritson	None		Wide range of food companies	Dean of the Faculty of Agriculture and Biological Sciences of the University of Newcastle-upon-Tyne, which has extensive teaching and research interests in food related areas.
Mrs B Saunders	J Sainsbury plc	Member of the Advisory Committee on Gene Technology	None	
Prof. S Shaw	Food From Britain	Council Member	Wide range of food companies	Deputy Principal & Professor of Marketing at University of Strathclyde which has extensive teaching and research interests in food related areas.
	Biotechnology & Biological Sciences Council	Member		
	Asda	Minor Shareholding		
	Cadbury Schweppes	Minor Shareholding		
	Scottish Agricultural Colleges	Non-executive director		

MEMBER	PERSONAL INTERESTS (i.e. those involving payment to the member personally) NAME OF COMPANY	NATURE OF INTEREST	NON-PERSONAL INTERESTS NAME OF COMPANY	NATURE OF INTEREST
Mr P W Strachan	Britivic Soft Drinks	Consultant	None	None
	Reckitt & Colman	Shareholder		
	Unilever	Shareholder		
	Marks and Spencer	Minor shareholdings		
	Leatherhead Food Research Association	Director		
	Norwich Research Park	Consultant		
Prof. H F Woods	None		Wide range of national and international food and chemical companies	Dean of the Faculty of Medicine, University of Sheffield, 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. Harry Bottom Charitable Trust, and Special Trustee for the former United Sheffield Hospitals.

Note: All these interests are current at 31 December 1997.

REGISTER OF INTERESTS: A CODE OF CONDUCT FOR MEMBERS OF THE FOOD ADVISORY COMMITTEE

INTRODUCTION

1. The FAC's work covers a wide range of issues which are connected with the food industry, and it is therefore desirable that its members 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

2. In this note, 'food industry' means:

- Companies, partnerships or individuals who are involved with the production, manufacture, packaging, sale, advertising, or supply of food or food processes, subject to the Food Safety Act 1990;

- Trade associations representing companies involved with such products;

- Companies, partnerships or individuals who are directly concerned with research, development or marketing of a food product which is being considered by the FAC.

3. In this code 'the Secretariat' means the Secretariat of the FAC.

DIFFERENT TYPES OF INTEREST

4. The following is intended as a guide to the kinds of interests which should be declared. Where members are uncertain as to whether an interest should be declared they should seek guidance from the Secretariat or, where it may concern a particular product which is to be considered at a meeting, from the Chairman at that meeting. **If members have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them.** However, neither

the members nor the Secretariat are under any obligation to search out links between company and another, for example where a company with which the member is connected has an interest in a food industry company of which a member is not aware and could not reasonably be expected to be aware.

Personal Interests

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

- **Consultancies**: any consultancy, directorship, position in or work for the food industry which attracts regular or occasional payments in cash or kind;

- **Fee-Paid Work**: any work commissioned by the food industry for which the member is paid in cash or kind;

- **Shareholdings**: any shareholding or other beneficial interest in shares of the food industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management.

Non-Personal Interests

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

- **Fellowships**: the holding of a fellowship endowed by the food industry;

- **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 their position or department eg:

(i) a grant from a company for the running of a unit or department for which a member is responsible;

(ii) 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);

(iii) 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.

- **Trusteeships**: any investment in the food industry held by a charity for which a 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

7. Some members of the Committee may, **at the time of adoption of** this code, or in the case of new members, of 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 members shall seek a waiver permitting them to disclose their 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.

8. Members shall not enter into new contractual obligations which would inhibit their ability to declare a relevant interest.

Declaration of Interests to the Secretariat

9. Members of the Committee, should inform the Secretariat in writing of their **current personal and non-personal interests,** when they are appointed 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 members have an on-going financial involvement with the food industry, eg if they hold shares in a food company, if they have a consultancy contract with the food industry, or if they are 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 interests,** and will be invited to complete a declaration form once a year. It is sufficient if changes in non-personal interests are reported in the annual declaration form following the change. (Non-personal interests involving less than £1,000 from a particular company in the previous year need not be declared to the Secretariat).

Declaration of Interests and Participation at Meetings

10. Members of the Committee are required to declare any direct commercial interest in matters under discussion at each meeting. Having fully explained the nature of their interest, the Chairman and members may at their discretion decide whether the member should participate further in the discussion. If it is decided that the member should leave the meeting he or she is first able to make a statement on the item under discussion.

Register of Interests

11. The Secretariat keeps a register of interests declared to it and publishes details each year in the Committee's Annual Report.

LIST OF ABBREVIATIONS

ACMSF	Advisory Committee on the Microbiological Safety of Food
ACNFP	Advisory Committee on Novel Foods and Processes
ADI	Acceptable Daily Intake
CMO	Chief Medical Officer
COMA	Committee on Medical Aspects of Food and Nutrition Policy
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
CSM	Committee on the Safety of Medicines
DH	Department of Health
EC	European Community
EU	European Union
FAC	Food Advisory Committee
FSA	Food Standards Agency
GM	Genetic Modification/ Genetically Modified
HACCP	Hazard Analysis of Critical Control Points
MAFF	Ministry of Agriculture, Fisheries and Food
3-MCPD	3-Monochloropropane-1,2-diol
PCBs	Polychlorinated biphenyls
QUID	Quantitative Ingredient Declarations
SCAN	EC Scientific Committee for Animal Nutrition
SCF	Scientific Committee for Food
TDI/TWI	Tolerable Daily Intake/Tolerable Weekly Intake
WHO	World Health Organisation
WPFA	Working Party on Food Authenticity

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