

Department of Health

Report on Health and Social Subjects

44



# The Nutritional Assessment of Novel Foods and Processes

Report of the Panel on Novel Foods of the Committee on Medical  
Aspects of Food Policy

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# Preface

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In 1991 the Committee on Medical Aspects of Food Policy (COMA) reconvened its Panel on Novel Foods to complete its review of the nutritional implications of Olestra; and to advise COMA on how best to assess the implications for the national diet of recent and possible future developments in novel foods and processes. This Report is a response to the second of those two charges. The Panel met on two occasions.

Given the rapid developments in food technology and the increasing likelihood of novel foods being introduced into the national diet to an increasing extent, the Panel recognised that a wider range of factors would have to be taken into account in their evaluation if proper consideration was to be given to the implications for public health. Both positive and negative evaluations are particularly important now that the evidence of the importance of diet in public health has led to the Government giving priority to encouraging changes in the average British diet with quantified targets.

The Panel has set general principles and criteria, as well as specific nutritional criteria to be used in the considerations of novel foods and food processes referred to COMA. These will also act as a guide to manufacturers in preparing submissions for evaluation.

I am grateful to the members of the Panel who have given generously of their time and knowledge, and to the Secretariat for their support.

**K C Calman**

Chief Medical Officer

Chairman, Committee on Medical Aspects of Food Policy

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# Committee on Medical Aspects of Food Policy: Panel on Novel Foods

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# 1. Introduction

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## 1.1 Background

1.1.1 In April 1989, at the request of the Food Advisory Committee (FAC), the Committee on Medical Aspects of Food Policy (COMA) accepted the remit to assess the nutritional implications and consequences of the consumption of Olestra, a sucrose polyester fat substitute to be used in food. COMA convened a Panel on Novel Foods (PNF) which submitted an interim report on Olestra to COMA in December 1990 and COMA adjourned the PNF pending the receipt of further information required from the manufacturers of Olestra to complete its considerations. All the requested information has not yet been received.

1.1.2 Since 1989 there have been rapid and significant advances in the development of novel foods, including those using the techniques of genetic modification. Novel food processes are also being developed. Manufacturers of such products of new technology are encouraged to submit them voluntarily to a joint Department of Health (DH) and Ministry of Agriculture, Fisheries and Food (MAFF) Committee—the Advisory Committee on Novel Foods and Processes (ACNFP)—for evaluation. If such a product is a food additive then it must be referred to the MAFF Food Advisory Committee (FAC) for clearance. Although both the ACNFP and FAC have nutritional expertise within their membership, they may seek further advice from COMA as may other Government committees. This may be specific advice on an individual food or food ingredient or may relate to general issues. The interrelationships of the various committees involved in assessing the safety of novel foods are given in Appendix I. As more new products are developed, the nutritional implications of such foods for the national diet will become greater and it is likely that COMA will be asked increasingly to provide other Government advisory committees with an expert assessment of the nutritional aspects of the introduction of such foods into the national food supply.

1.1.3 The PNF was reconvened by COMA in May 1992 in order to consider the new information expected on Olestra. At that time COMA also asked the PNF to consider how best to assess the nutritional implications of current and possible future developments in food technology.

## 1.2 Terms of Reference of the Panel

“a. To advise the Committee on Medical Aspects of Food Policy on the nutritional implications and consequences of including Olestra in the diet.

b. to recommend to COMA how best to assess the implications for the national diet of recent and possible future developments in novel foods and processes.”



This report deals only with the second part of the Terms of Reference. A separate Report will be prepared on the first part when the Panel has been able to complete its assessment of Olestra.

### **1.3 Perspectives of the Panel**

1.3.1 The Panel decided to base its deliberations on the premise that diet has an important impact on health. Normal diets contain a host of nutrients as well as other compounds which can have a wide range of effects on the body and in particular, which can modify the body's response to dietary components or modulate both hormonal and other metabolic processes. The effects may be acute and lead to immediate subjective symptoms or could be chronic with long-term pathophysiological changes.

1.3.2 Nutrition, traditionally concerned with the intake of nutrients needed for the avoidance of nutritional deficiency diseases, now assesses the sustained effects of macro- and micro nutrients on health over decades. Undesirable effects of high intakes of both macro- and micro nutrients are described and the boundaries between toxicology and nutrition are becoming blurred since dietary factors may alter the absorption, metabolism and excretion of toxicants as well as modify their effects. The increasing recognition that dietary bioactive molecules have a multiplicity of actions which, although physiological, may entrain sustained changes in metabolism of pathological significance, also blurs the boundary between nutrition and toxicology. Considerable inter-individual variation in response to dietary compounds is apparent, with subtle toxicological changes being found in susceptible individuals eating a diet which would be considered healthy for others. The recognised interactions between dietary constituents means that the interpretation of data on the effects of any single dietary constituent is very complex.

1.3.3 The Panel was aware of the enormous range of recently introduced novel foods and food processes and of the potential for many more to emerge in the future. The Panel recognised that scientific progress and the development of biotechnology have intrinsic merit, and that novel foods and food processes are potentially at least as acceptable as any other food. However, their novelty is a special attribute which sets them apart from foods which have an established place in the diets of people in the UK.

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## **2. Examples of Nutritional Issues Arising from Novel Foods and Processes**

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### **2.1 Introduction**

There are a number of novel foods and processes that have been submitted for evaluation by ACNFP, and other Government Committees. Some of these raise an number of nutritional issues and represent the very wide range of new issues which could come before COMA and the PNF. The following categories contain some products already referred to COMA for assessment and on which separate Reports will eventually be made. Only general issues raised by novel foods and food processes are addressed in this section.

### **2.2 Fat Substitutes**

2.2.1 A variety of fat substitutes have been developed by the food industry in recent years, primarily as a response to increasing concern about the association between levels of fat consumption in Western societies and the occurrence of coronary heart disease (CHD) and obesity. Some fat substitutes are already in use, whilst others remain subject to approval, awaiting appraisal of their safety. Although it is relatively straightforward to assess the short-term physiological effects of consuming fat substitutes, their overall effects on the total diet of the population as a whole or of particular sub-groups is difficult to predict.

2.2.2 Fat substitutes can be divided into two main categories: those that are carbohydrate or protein based such as modified starches, gums and the microparticulated egg and milk protein "Simplese"; and those that are lipid based such as sucrose polyesters eg Olestra. The carbohydrate and protein based compounds are limited in their application since many are not heat stable and do not provide all of the desirable characteristics associated with fat in food. In contrast, lipid based substitutes have functional and sensory properties similar to the fats they replace and so have the potential for wider use. So far only Olestra has been put forward as a possible lipid based fat substitute suitable for incorporation in food and the Panel has already carried out a preliminary assessment of the nutritional implications.

2.2.3 The Panel considered the most appropriate way to achieve good health and the dietary targets (DH, 1992) is the lifelong adoption of a diet less rich in saturated fatty acids and total fat, together with a pattern of lifestyle to avoid obesity. The rationale of the food manufacturers for the development of fat substitutes is to help reduce the contributions of total fat and saturated fatty acids to dietary energy, and thereby reduce the risk of coronary heart disease (DH, 1991, 1992). Many individuals could find products containing fat substitutes a valuable contribution to a lower fat

diet. The Panel have recognised this as one approach to such dietary changes, but felt unable to endorse at this stage the use of fat substitutes as an effective way of achieving a lifelong reduction of risk of diseases related to dietary fat.

2.2.4 Lipid based fat substitutes are intended to pass through the gastrointestinal tract without being hydrolysed or absorbed and may therefore act as a pool of solvent for other lipophilic materials throughout the length of the gut. Whereas this may be of benefit to the individual if, for example, cholesterol were sequestered in this pool and eventually lost to the body, their consumption may subsequently lead to a reduction in the absorption of the fat soluble vitamins A, D, E and K. Further, the introduction of new fat substitutes and their range of application could increase both the amount of fat substituted in food and the range of products into which fat substitutes could be incorporated. An increasing use of fat substitutes in food therefore has significant potential to alter the overall composition of the diet and would have a different impact on micronutrient intakes from that expected from an increase in complex carbohydrate intake.

2.2.5 The Panel has made additional observations on the effect of fat substitutes on individual nutrients and these are given in detail in Appendix II.

### **2.3 Interesterified fats (restructured triglycerides) for use in pre-term and infant formulas**

2.3.1 The ACNFP has already recommended to Ministers that fats produced by a particular enzyme catalysed interesterification process are acceptable for use as “an ingredient in chocolate confectionery or as a component at levels of up to 20% in frying fats, provided that such a use does not increase saturated fat intake” and that “the lipase enzymes have been cleared by the FAC and the COT for use in food” (ACNFP, 1991).

2.3.2 A submission has also been made to the ACNFP on the use of such a process using enzymes to change the fatty acids on the 1 and 3 positions on a triglyceride molecule, without affecting the 2 position, to produce a restructured triglyceride mixture with a fatty acid profile closely resembling that of human breastmilk fat, for use as an ingredient in pre-term infant formulae.

2.3.3 This is the first time that the ACNFP have been asked to consider the safety of an ingredient intended for incorporation into infant formulae. It was agreed to refer the question of acceptability of restructured triglycerides produced in this way to COMA and the PNF, who would be expected to consult closely with the COMA Panel on Child Nutrition before making any recommendations.

### **2.4 Fructo-oligosaccharides**

2.4.1 Fructo-oligosaccharides (FOS) produced by the enzyme-catalysed addition of 1 to 3 fructose molecules to a sucrose molecule, have the potential to be used as a total or partial replacement for sugar in certain foods since they provide both bulk and sweetness. In addition FOS may be poorly metabolised and so provide less energy than the sugar they are intended to replace.

2.4.2 Under current UK and EC labelling law, FOS must be categorised as carbohydrate on food labels. As a single energy value for all carbohydrates has been laid down in food law, “reduced calorie” claims are not permitted unless legislation is changed. Claims for “reduced sugar” might be allowed.

2.4.3 The FAC has categorised FOS as food additives (see Appendix I) and has now formally asked COMA for an assessment of the nutritional consequences of their ingestion, including an assessment of the suitability of FOS for use by diabetics.

## 2.5 Caprenin

2.5.1 The ACNFP has recently received a submission regarding a novel fat in the UK for use as a replacement for cocoa butter and confectionery fats. Caprenin is the name given to a triglyceride of the generic chemical name “*caprocapylobehenin*” and is composed of the medium chain fatty acids capric (C8:0), and caprylic (C10:0), with some very long chain fatty acids, primarily behenic acid (C22:0). The behenic acid is in the 1 position on the glycerol molecule with a mixture of capric and caprylic acids in the 2 and 3 positions. Because behenic acid may be only partially absorbed, the manufacturers claim that the calorific value of Caprenin is on average only 5 kcal/g, as compared to about 9 kcal/g for conventional dietary fats.

2.5.2 It is claimed that the lower calorific value for Caprenin, coupled with its physical and chemical properties, could make it suitable as a reduced calorie substitute for the cocoa butter and hydrogenated vegetable oil-based products currently used in chocolate and chocolate confectionery (including fillings, and chocolate coatings for biscuits and wafers).

2.5.3 There are several nutritional issues raised by the possible use of this product but the fatty acid composition may be considered to be particularly significant. The manufacturers estimate that if Caprenin were to replace all appropriate confectionery fat, the estimated mean intakes of capric, caprylic and behenic acids, would be between two and four times the current intakes of fatty acids though it would still represent only about 6 per cent of total dietary fat intake. The manufacturers also claim that the consumption of Caprenin is not likely to induce hypercholesterolaemia since the consumption of its individual constituent fatty acids would not affect blood cholesterol levels. In addition, the predicted maximum Caprenin intake is not likely to represent a major proportion of total dietary fat intake. However, at present there are no clinical data specific to Caprenin itself although studies are under way.

## 2.6 Ohmic heating

2.6.1 The ACNFP has been asked to consider the consumer safety aspects of ohmic heating applied to food processing. In commercial ohmic heating a cooked, sterile end product is obtained by pumping semi solid food through a series of electrodes between which an alternating electric current flows.

2.6.2 In common with many other techniques for cooking and sterilising food, ohmic heating can give rise to loss of vitamins, particularly vitamin C. The ACNFP has concluded that the dietary impact of any additional vitamin losses during ohmic

heating will be minimal compared with conventional processes. For the foreseeable future the process seems likely, for commercial reasons, to be applied only to particulate-containing, pumpable foods such as ready made meals which on average are not, at present, a major source of vitamins in the diet. Currently, the ACNFP has advised restricting the use of ohmic heating to such foods (ACNFP 1991). For some people the contribution of such foods to the total diet may be substantial and the ACNFP has recommended that it should be reconsulted before the process is used under other conditions and that the appropriate data be made available to it. In particular, if it is desired to extend the range of products to be processed and apply the process to foods of greater nutritional importance, then data will be necessary to enable the nutritional impact to be evaluated (ACNFP, 1991).

## **2.7 Sugar beet fibre**

2.7.1 An application has been considered by the ACNFP for approval of a novel product which contains 30 to 50 per cent of a soluble dietary fibre derived from sugar beet and 25 to 45 per cent sucrose. It can be incorporated into sugar to give granulated packet sugar that is suitable for sweetening and home baking purposes. The proposed level of inclusion in sugar is 5 to 7 per cent which the manufacturers calculate to be approximately equivalent to 2 to 2.8 per cent fibre. It is not clear whether the fibre can be expressed as non-starch polysaccharides (NSP) or whether the product has an insoluble as well as a soluble fibre component. Estimates of intake based on these inclusion levels provide a calculated maximum intake of this fibre of 2.1 g/person/day, and 2.4 g/person/day if it were also used as an ingredient in certain manufactured food products.

2.7.2 Although there is little data on previous human exposure to the product itself, there is a long history of the use of sugar beet as a source of sugar for human consumption. In addition, the pulp remaining after sugar extraction has a long history of use as an animal feeding stuff. There have been a number of animal and human volunteer studies using this product and another sugar beet dietary fibre product; both products failed to show any effect on the diet other than those expected when the fibre content of the diet is suddenly increased. There are however a number of effects on micronutrient uptake which need to be assessed and the impact of this specific form of soluble fibre on intestinal function has not been fully evaluated.

2.7.3 The Panel also considered that the development of such products raises questions as to the appropriateness of using a food such as sugar, whose consumption COMA has advised should fall (DH, 1991), as a vehicle to increase the consumption of fibre.

## **2.8 Genetic modification**

2.8.1 Conventional plant breeding is uncertain and can take many years to produce desirable genotypes. For crops and microorganisms, more advanced techniques have been developed in the last 50 years which increase the chance of a change in the DNA, although they still depend on the chance occurrence of a useful mutation.

2.8.2 It is now possible to identify genes that code for particular desired characteristics and then to extract and insert them into the desired organism without breeding. Genetic modification, which is also commonly known as “gene splicing” or “genetic engineering”, refers to such removals or insertions of genes. Progress in developing and applying genetic modification in the agriculture and food industries (amongst others) is now taking place in many countries.

2.8.3 Genetic modification makes it possible to transfer genes between species that do not usually breed with one another. This could, for example help plant breeders make potentially useful changes to crops which are at present difficult to make, eg increasing the level of vitamins within a plant. Genetic modification might therefore provide consumers with a greater variety of foods, and a food supply of improved nutritional quality.

2.8.4 Transgenesis (the name given to the process of introducing DNA from one species into the genome of another) can also be applied to several species of large animal. Such application involves microinjection of a few hundred molecules of foreign DNA into one of the two pronuclei of an embryo. It may be able to provide a genetic route to developing farm animals that are disease resistant, produce lean meat, or grow more efficiently. At present, the production of therapeutic proteins from transgenic animals is a profitable commercial business. For example, transgenic sheep possessing the gene for human alpha-1-antitrypsin (AAT) produce the human protein in their milk.

2.8.5 A recent report by a joint FAO/WHO Consultation (WHO, 1991) considers that on the basis of their review of known or suspected hazards, transgenic animals should not cause any significant concern from the point of view of food safety, although they recognised that food intolerances and allergies might be a potential hazard.

2.8.6 The potential nutritional significance of genetic modifications to the food supply is, at present, uncertain. Nevertheless, the Panel considered that transgenesis has the potential to produce food with a significantly altered nutritional composition or quality, which should be monitored from a nutritional perspective.

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## **3. Clearance of Novel Foods in the UK and the EC**

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### **3.1 Clearance in the UK**

All foods including novel foods are currently controlled in the UK under the provisions of the Food Safety Act 1990. Pre market clearance of novel foods and food processes is not part of the Act and is voluntary; manufacturers are therefore free to market their products subject only to the requirements of the Act but are encouraged to submit for clearance. Clearance of a food or food process does not constitute formal approval; rather it is a confirmation that on the evidence presented, Ministers see no food safety reason why the food should not be legally marketed in the UK. The Food Safety Act 1990, contains powers to enable Ministers to introduce some controls on foods to protect public health. In addition there is European Community (EC) activity in this area.

### **3.2 Clearance in the European Community (EC)**

Currently the EC is planning a twin-track approval system under which those foods which raise the most significant potential food safety concerns could be assessed centrally by the EC Scientific Committee for Food (SCF). Other novel foods would be assessed by experts nominated by Member States. To this end the European Commission has issued a draft Council Regulation on Novel Foods and Novel Food Ingredients (EC Commission, 1992) and a Council Directive on Scientific Co-operation (EC Commission, 1993).

#### **3.2.1 EC Council Regulation**

This Regulation is a draft and may be subject to considerable change. However, it currently proposes a scheme whereby those responsible for placing novel foods on the market and regulatory authorities may identify those cases where there is a need to evaluate scientifically a food which is being offered for sale for the first time, either because it contains ingredients that have never been consumed as food before, or because it has been changed fundamentally by the use of new physical, chemical or biological techniques. It also lays down procedures for evaluating scientifically these novel foods or ingredients and identifying those cases where no existing assessment criteria are available. Foods or processes with an established history of safe use will not fall under this draft Regulation but it lays a duty of care on those marketing a new product which falls into any of its designated categories to carry out a scientific assessment of the food. This will be carried out either by the SCF or by an expert, that is a person with the appropriate expertise to evaluate any changes in the nutritional value, digestibility, stability, hygienic quality, or content of possible undesirable substances. Where the expert considers that the information available shows that the food can be evaluated by accepted methods with the conclusion that the food is

acceptable for marketing, then the product may be marketed, with a notification sent to the Commission. However, should the Commission or a Member State consider that the safety questions have not been adequately answered they may require the product to be subjected to examination by the SCF. In this case the details of the assessment will be examined by the SCF before authorization for placing on the market is given. The draft Regulation contains an annex setting out general criteria for the placing on the market of novel foods. These are that:

- they are safe for the consumer when consumed as food at the intended levels of use;
- they do not mislead the consumer;
- they do not differ from similar foods or food ingredients that they may replace in the diet in such a way that their normal consumption would be nutritionally disadvantageous for the consumer.

### 3.2.2 EC Council Directive on Scientific Co-operation

This Directive, which it is anticipated will be adopted shortly, relates to all food safety matters referred to the SCF, including food additives, food contact materials and novel foods and food processes (EC Commission, 1993). If advice on a novel food or process needs to be sought from the SCF then the following procedures will take place:

- i. EC Standing Committee for Food will be asked to nominate a body, institute or expert individual in one of the Member States to prepare a paper for the SCF. Any body/institute/individual nominated to prepare a paper may refuse if they do not have sufficient resources. Similarly, the Commission cannot allocate a task to a body/institute/individual in a Member State if its parent national authority does not agree. In the case of the UK, the national authority is the Government, represented by the Department of Health (DH) and the Ministry of Agriculture, Fisheries and Food (MAFF).
- ii. The SCF will nominate a rapporteur from its plenary Committee to liaise with an author(s) of the paper and the rapporteur will present the paper at the SCF meeting.

The UK is normally represented by MAFF at the Standing Committee, but DH will also attend those meetings where any discussions on allocation of work to Member States under the Co-operation Directive procedure takes place. This should ensure that the capabilities of the various agencies in the UK and other Member States will be able to have an input to the nominating process. Where the UK is nominated to prepare a paper, the ACNFP would be the body consulted on submissions relating to novel foods and processes and it would consult COMA as necessary.

If the SCF opinion was favourable then the novel food or ingredient would be authorised for marketing EC wide. The ACNFP would be the body consulted on submissions relating to novel foods and processes and it would consult COMA as necessary.



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## 4. The Nutritional Assessment of Novel Foods

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### 4.1 Background considerations

4.1.1 New raw materials for food, and new processes for the production of food, are rapidly evolving from the research stage to the market place. These new materials may be modified food components, synthetic substances, or new raw materials that are derived from animals, plants or microorganisms. One important element in the production of these is the application of techniques of genetic technology. New materials and technologies are under development with the aim of improving nutritional quality, enhancing the taste, smell, texture or appearance; or rendering more effective the production, storage or processing of food.

4.1.2 The approval of novel foods and processes and their range of application could affect different population groups experiencing wide variations in exposure. Their increasing use therefore has the potential to alter significantly the overall composition of the diet.

4.1.3 The Panel was very aware that future nutritional assessments of novel foods would be carried out against a background of rapidly advancing knowledge of the role of diet in the causation and prevention of many diseases from classical nutrient deficiencies to diseases such as CHD and cancers. In recognition of the importance of the diet in determining the patterns of mortality and morbidity, the Government has set dietary and nutritional targets to reduce total fat and saturated fatty acid intakes and the prevalence of obesity in its White Paper on the Health of the Nation (DH, 1992).

4.1.4 The Panel considered the nutritional implications of novel foods against the background of this White Paper, and noted that at present there is no requirement for the Government to approve novel foods for use. Reference to the Government advisory committee, the Advisory Committee on Novel Foods and Processes (ACNFP), is voluntary. Up to now considerations of food safety have been limited to their potential for producing acute and chronic toxic effects or nutrient deficiency. The issue of the influence of one particular food or food ingredient on the risk to a population of developing a chronic disease would be a departure from previous practice.

4.1.5 The Panel considers that novel foods have the potential to influence dietary habits in ways which can be either beneficial, leading to decreased risks for chronic or other diseases, or adverse, leading to increased risks for the populations consuming them. The Panel therefore concluded that in assessing the nutritional implications of novel foods or food processes, the potential impact on public health should form a

major and integral part of the Panel's Terms of Reference. The Terms of Reference should also be flexible enough to accommodate future new developments in knowledge about diet and disease.

## **4.2 Criteria for assessment**

In deciding general criteria the Panel endorsed the following recommendations based on the conclusions of a joint meeting of the ACNFP and the Committee on Toxicity (COT) regarding the assessment of a novel food for:

- a. its intrinsic acute and chronic effects, and for the effects of novel foods on the intakes and handling of recognised toxicants in the diet;
- b. both intrinsic metabolic effects and in comparison with any primary ingredient it might replace;
- c. its effect on the composition of the diet as a whole, and the range of such effects;
- d. the potential for change in the nutritional profile of the national diet.

## **4.3 General principles**

The Panel agreed that the following general principles should guide the nutritional assessment of novel foods and processes. Some of these criteria are adapted from proposals by the Organisation for Economic Co-operation and Development for the evaluation of foods developed using the techniques of biotechnology (OECD, 1992).

- a. novel foods and food processes have the basic attribute of their novelty. They may or may not be intended as a substitute for an existing food, but in either case they must be considered in as broad a context as possible;
- b. the starting point for assessment of novel foods should normally be a comparison with an existing food. Novel foods should be at least as safe, and, if possible, safer than comparable foods if such foods exist;
- c. the assessment of novel foods and food processes should identify potential advantages and disadvantages from their introduction to the food supply, taking account of their composition, likely contribution to the diet and any particular preparation or cooking requirements;
- d. a history of safe use if available from elsewhere in the world, should be incorporated into the nutritional assessment. However the adequacy in the database needs to be taken into account in the consideration;
- e. novel foods should be considered both in the context of the whole diet and the human response to that diet and in the context of the responses of potentially vulnerable groups such as children and pregnant or lactating women. The overall diet should be safe, wholesome and nutritious;
- f. foods derived from genetically modified sources should be assessed in a similar manner to those produced by conventional techniques;
- g. where clearance is limited to use in a specified food product or range of products, if a further use is subsequently proposed, then the novel food should be submitted for re-evaluation;

- h. the inclusion of a novel food in the diet should not lead to a change in the diet such that the likelihood of disease is increased. These effects may be of two forms:
  - i. direct metabolic or other actions on pathophysiological processes;
  - ii. relationships and interactions between nutrients, and between nutrients and known toxicants, likely to be present in the diet.

#### **4.4 Nutritional criteria**

The Panel stressed the need to assess a novel food specifically from a nutritional standpoint and propose that the following framework should include:

- a. the dietary significance of the novel food;
- b. the nutrient content of the diet as eaten containing the novel food, and the content of any antinutritional constituents (such as trypsin inhibitors) that may be introduced into the diet with the novel food;
- c. the bioavailability of the nutrients in the novel food itself, the food's possible effects on other components of the diet, such as the mineral content, and any implications of possible changes that might be induced in the gut microflora;
- d. the effects of the novel food on the bioavailability of nutrients from other foods in the diet;
- e. the quantitative effects and/or dose response relationships of the novel food in relation to gut and systemic functions.

#### **4.5 New Terms of Reference for the COMA Panel on Novel Foods**

4.5.1 The Panel propose the following Terms of Reference which should allow for the proper consideration of novel foods and processes already referred to COMA for nutritional assessment and future new products and developments arising through developments in food technology. They take account of the various principles and criteria endorsed by the Panel.

“To advise on the implications of novel foods and food processes for public health, taking account of:

- a. the impact of novel foods and food processes on the nutritional safety of the diet;
- b. the impact of novel foods and food processes on metabolic pathways and physiological functions in humans which may have either beneficial or adverse effects on the long term health of the population and of potentially vulnerable subgroups;
- c. the impact of the introduction of novel foods and food processes on the nutritional value of the diet in relation to current dietary recommendations and national targets.”

4.5.2 In following these Terms of Reference the Panel will take account of all the criteria for assessment, general principles, nutritional criteria and further considerations in paras 4.2-4.4. These will also be a useful guide to manufacturers whose products have been referred to COMA for nutritional assessments in preparing scientific submissions for evaluation by the Panel.

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# Appendix I: Government Committees which assess aspects of the safety of novel foods

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Several Government committees have responsibility for the assessment of the safety of novel foods. The interrelationships of these Government committees are outlined below:

## 1. The Advisory Committee on Novel Foods and Processes (ACNFP)

The ACNFP is an independent body of experts appointed by MAFF and DH Ministers. Its terms of reference are:

“To advise Health and Agriculture Ministers of Great Britain and the Heads of 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”.

At present the ACNFP operates a voluntary safety evaluation scheme for novel foods and processes. New EC Regulations may make safety evaluation of all novel foods and processes statutory.

Although the ACNFP has nutritional expertise (the Chairman and two members of the PNF are members and there is an Observer representing the COMA Secretariat) its Terms of Reference permit the committee to take account of the views of other Governmental expert advisory committees. These include COMA and Annex 1 is the ACNFP document which lays out the relationship between ACNFP, COMA and the FAC as well as other Committees. The annex demonstrates how the ACNFP can consult when:

- i. additional expert advice is needed to complete an evaluation;
- ii. a need is perceived for dietary surveillance; or
- iii. an assessment is necessary of any likely impact of a new product on the total diet of the population as a whole or of particular sub-groups.

For example, ACNFP has received an application for clearance of enzyme catalysed interesterified fats for use in infant formulas. As infant formulas constitute a highly specialised areas of nutrition the Committee is seeking the advice of COMA on this issue.

## **2. The Food Advisory Committee (FAC)**

The FAC is an expert advisory committee appointed by MAFF Ministers in consultation with DH and Territorial Ministers. Its Terms of Reference are:

“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. 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”.

The FAC currently has nutritional expertise and medical and scientific members of the COMA Secretariat routinely attend as observers. However, as a part of its Terms of Reference FAC takes account of the advice of other relevant advisory committees including COMA. In the case of Olestra the FAC accepted a case of need for Olestra as a food additive and asked COMA for advice on the nutritional implications and the Committee on Toxicity (COT) on the toxicological safety of the product.

## **3. The Committee on Toxicity (COT)**

The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) is an expert committee appointed by CMO to advise him. It has an independent Chairman who is also a member of both ACNFP and FAC. The COT has nutritional expertise. Its Terms of Reference are:

“1. At the request of Government Departments to assess and advise on the risk to humans of toxicity from substances which are:

- a. used or proposed to be used as food additives, or used in such a way that they might contaminate food through their use or natural occurrence in agriculture, including horticulture and veterinary practice or in the distribution, storage, preparation, processing or packaging of food;
- b. used or proposed to be used or manufactured or produced in industry, agriculture, food storage or any other workplace;
- c. used or proposed to be used as drugs, when advice its requested by the Medicines Commission, Section 4 Committees or the Licensing Authority;
- d. used or proposed to be used or disposed of in such a way as to result in pollution of the environment.

2. To advise on important general principles or new scientific discoveries in connection with toxic risks, to co-ordinate with other bodies concerned with the assessment of toxic risks and to present recommendations for toxicity testing.”

## **4. Committee on Medical Aspects of Food Policy (COMA)**

COMA is a committee of experts appointed and chaired by the Chief Medical Officer. It provides independent advice on matters relating to nutrition, diet and health. Its Terms of Reference are:

“To consider and advise on:

- a. the medical and scientific aspects of policy in relation to nutrition;
- b. at the request of, or in association with, appropriate advisory committees, the medical and nutritional aspects of developments in the agriculture and food industries including the production and processing of food;
- c. at the request of the Department of Health matters falling within these terms of reference.”



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# Appendix II: Fat Substitutes and Individual Nutrients

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## 1. Total Fat and Energy

Manufacturers claim that the consumption of fat substitutes would be accomplished with little or no compensatory intake of energy from alternative food sources, thus aiding an individual in weight control. In addition, they claim that levels of total fat in the diet will also be reduced without significant compensation, in line with current dietary recommendations. However, there is little or no evidence that any energy deficit or reduction in fat created by the consumption of food containing fat substitutes would not be compensated for by increased consumption of other foods, and it is probable that at least some energy and fat compensation would occur. If such foods were covertly to reduce fat and energy intake this may have undesirable, or even potentially dangerous, implications for certain groups of the population such as children, adolescents or the elderly who might need a diet particularly rich in energy and nutrients. Groups who might be expected to incorporate fat substituted foods into their diets at a relatively high level such as female adolescents may also be at particular risk.

## 2. Essential Fatty Acids

Fat obtained from food is needed by the body as a source of essential fatty acids (EFA). EFA deficiency is rare since only a very small amount of fat is needed for this purpose so it is unlikely that a deficiency of EFA would arise as a result of the widespread use of fat substitutes.

## 3. Polyunsaturated Fatty Acids

Despite the claims of the manufacturers, it is possible that large amounts of polyunsaturated and monounsaturated fatty acids rather than saturated fatty acids, would be replaced by lipid based fat substitutes in food, especially if such fat substitutes are incorporated into vegetable cooking oils. These changes would then have important nutritional implications for coronary heart disease (CHD) prevention.

## 4. Fat Soluble Vitamins

There is concern that the presence of non-absorbable, lipid based, fat substitutes in the gut might lead to an interference with the absorption of fat soluble vitamins. Various short term studies on Olestra, for example, have indicated a reduction in the level of vitamin E in the plasma, and vitamin A in the liver. These changes might reflect a decrease in the total body pool of vitamins, or changes in plasma lipid

transport secondary to a decrease in total fat absorption. The manufacturers have subsequently proposed supplementation of Olestra with vitamin E. Further information on the long term consequences of Olestra on the body status of vitamin A and other fat soluble vitamins has been requested.

## **5. Plasma cholesterol**

A number of studies on humans have demonstrated that the ingestion of Olestra can reduce plasma cholesterol by 4 to 15 per cent. The observed decreases were primarily in LDL-cholesterol, with little effect on HDL-cholesterol, and appear to exceed the effectiveness of simply reducing fat or cholesterol intakes, especially in hyperlipidaemic individuals. However the reduction of plasma cholesterol has only been seen at levels of intake of Olestra higher than those expected to be obtained from food. Therefore Olestra might only be of benefit if present in large amounts. Further information on the effect that Olestra has on plasma cholesterol had been requested, in particular whether there is evidence of a threshold effect, a dose/response relationship, or an enhancement of the effect at high intakes.

## **6. Food Choice**

The effect that inclusion of fat substitutes in foods might have on eating habits and food choice is difficult to predict. Unlike many experimental studies on the effect on eating behaviour, in real life consumers are aware of the reduced fat content of the substituted foods they consume and may therefore, as a result of this knowledge, be subconsciously or consciously compensating for it by consuming alternative sources of energy and/or fat. The presence of fat substituted products on the market might encourage consumption of foods which because of their perceived high fat/energy content, would normally be avoided or considered as treats for occasional use. These behavioural issues need to be recognised if a product is developed to improve individual and public health by altering the nature of the diet.

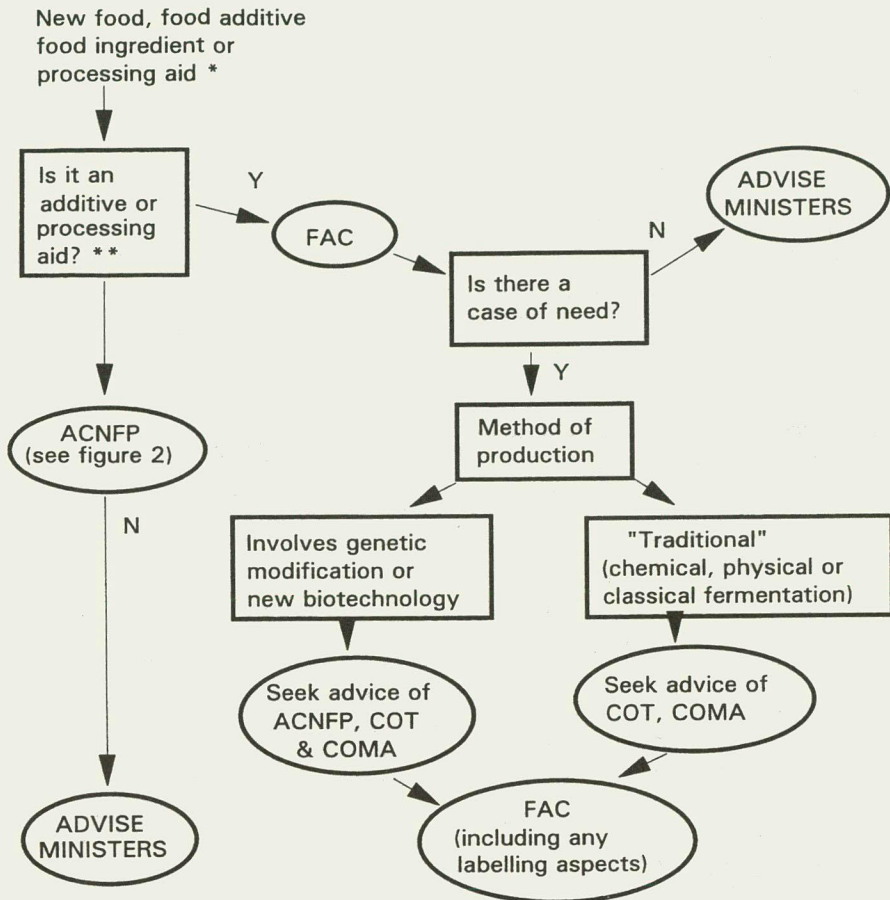
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# **Annex I. Advisory Committee on Novel Foods and Processes: Relationships with Other Expert Committees**

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1. Several expert committees advise Government on aspects of food safety. Whilst these committees each have their own areas of responsibility, it may be necessary for them to refer particular products to other committees for their specialist advice.
2. A decision tree to assist in the allocation of the primary responsibility for a submission to either the ACNFP or the Food Advisory Committee (FAC) is shown in Figure 1. A diagram shown in Figure 2 describes the relationship of the ACNFP with COMA, and with other expert committees. These two documents are complementary; they are intended primarily for use by officials determining the route of evaluation of a particular submission. They are also made available to the public, on request.
3. The ACNFP assesses the nutritional impact of individual novel foods and processes to check any effects on safety in use. Where there are nutritional implications of concern, the committee may either approve the use of a novel food in a particular range of uses only, or recommend that the effect on the nation's diet should be monitored. The ACNFP has within its membership a range of expertise, including nutrition. It will, however, seek the advice of COMA if the nutritional concerns are such that a more detailed assessment is needed than can be provided by the ACNFP alone. The ACNFP would also remit to COMA any need for long term surveillance on the population as a whole or on selected groups.

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

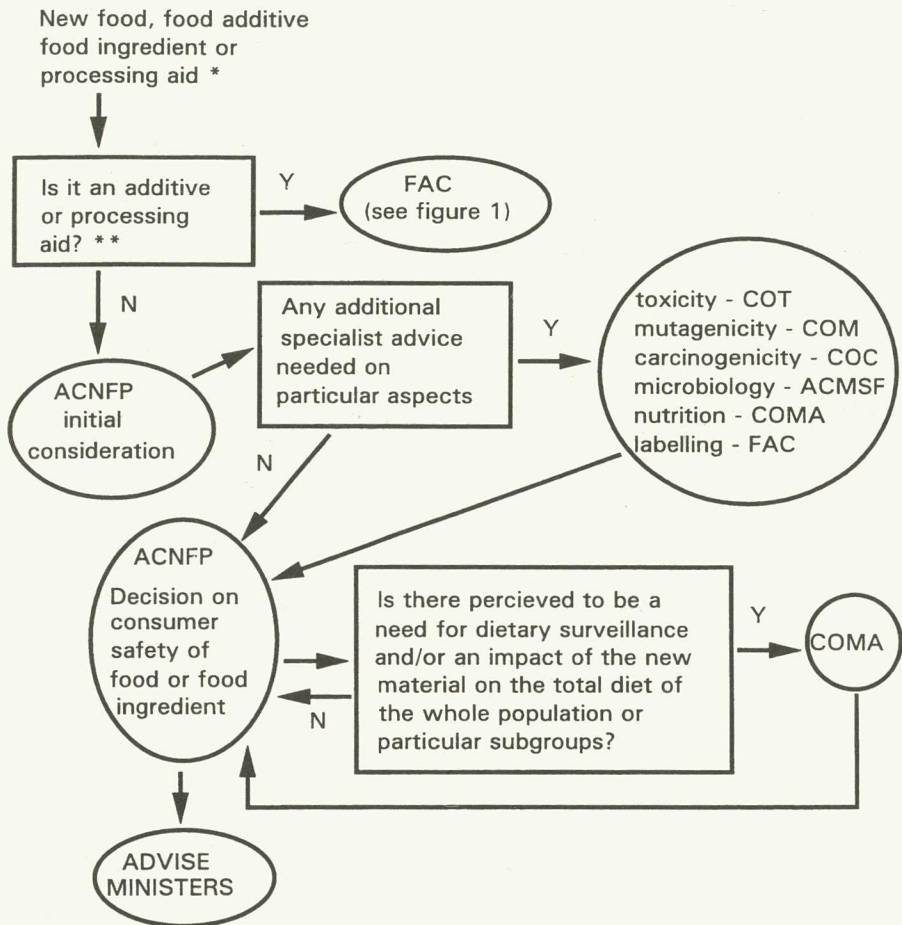


\* If a medicinal licence has been applied for, or any medical claims are made for the product, then the Medicines Control Agency will need to be consulted.

\*\* Using definitions from Council Directive 89/107/EEC of 21/12/88 - Additives Authorised for Use in Foodstuffs Intended for Human Consumption

Use of this decision tree will involve consideration of the extent of use (with implications for dietary intake), whether other uses are likely to result in a changed classification giving a different route of evaluation and the status of the substance with respect to existing additive regulations.

Figure 2 : Relationship of ACNFP with other expert committees involved in the assessment of food safety



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



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