NOVEL FOODS: BEYOND NUFFIELD

The second report published by

FOOD ETHICS COUNCIL

THE INDEPENDENT COUNCIL FOR ETHICAL STANDARDS IN FOOD AND AGRICULTURE

GENERAL INTRODUCTION

Why a Food Ethics Council?

It can hardly be doubted that food is a matter of ethical concern. We all need it, in adequate quantity and of adequate quality, to survive and maintain health. The fact that millions of people are malnourished, even to the point of starvation, while others are preoccupied with dieting to lose weight, is evidence enough that there is something seriously wrong with the ethics of global food provisioning.

But ethical concerns are not confined to such disparities, startling as they are. The production of food in modern agricultural practice often has quite damaging effects on the environment, e.g. in terms of soil erosion, chemical pollution and reduced biodiversity. Exploitation of animals for food is considered by some to be wrong under any circumstances and by others to seriously infringe the acceptable levels of animal welfare when animals are kept in certain intensive systems. The ways in which food is grown, processed and marketed also arouse deep concerns, particularly when they involve certain modern biotechnologies, such as genetic modification.

Following the Uruguay round of talks of the General Agreement on Tariffs and Trade (GATT), the European Parliament adopted a resolution[1] which emphasised:

"the need for the WTO (World Trade Organisation) to link trade issues to environmental, social and animal protection issues with the aim of accommodating conflicting interests and insists that WTO decisions must on no account be permitted to threaten existing international or EU standards."

This is a clear statement of intent to incorporate ethics into public decision making. It has, however, made little impact to date, mainly, we suggest, because few attempts have been made to proceed from this general expression of good intent, first to a rigorous analysis of the ethics of food production, and then to a series of practical recommendations for good practice. The Food Ethics Council has been established to address this need.

The Food Ethics Council: General Aims

In 1998, in response to an initiative from the Farm and Food Society, the Joseph Rowntree Charitable Trust made funds available to establish a Food Ethics Council; a group of independent individuals (see Box: Members of the Food Ethics Council) chosen to provide the range of expertise needed to address the following aims:

- *Review developments in food and agriculture within a sound framework of practical ethics which addresses the principles of wellbeing, autonomy and justice with respect to consumers, producers, farm animals (where relevant) and the living environment.*
- *Promote the incorporation of ethical thinking in decision-making in agriculture, food manufacturing and retailing*
- *Produce authoritative, well-researched reports, which highlight ethical concerns and make recommendations for action.*

Members of the Food Ethics Council

Ms Helen Browning: Organic farmer; Chair of the Soil Association, Wiltshire
Prof Ruth Chadwick: Professor of Moral Philosophy; Director of the Centre for Professional Ethics, University of Central Lancashire
Dr Paul Ekins: Director of Forum for the Future; Reader in the Department of Environmental Social Sciences, University of Keele
Mrs Janet Graham: Vice-President of the National Federation of Consumer Groups, Sussex
Ms Suzi Leather: (Vice Chair) Chair of a Community NHS trust; consumer affairs specialist, Exeter
Dr Peter Lund: Senior Lecturer in the School of BioSciences, University of Birmingham
Dr Ben Mepham: (Executive Director) Director of the Centre for Applied Bioethics, University of Nottingham
Mr John Verrall: (Treasurer) Pharmaceutical chemist, Sussex
Prof John Webster: (Chair) Professor of Animal Husbandry, University of Bristol Veterinary School

1 Official Journal of the European Communities (1994) C18/165 : European Parliament DGI - Legislative Planning Division - Resolution (no. 23) on the conclusion of the Uruguay Round and the future activities of the WTO (15.12.94)

Summary of Recommendations

1. Any application for the marketing of a Novel Food in the UK should be subject to a comprehensive ethical assessment of its potential socioeconomic and environmental impacts (in addition to the existing safety assessments) employing an agreed ethical framework, such as the Ethical Matrix used in this report (3.2). Advice should be sought from a broad range of expertise, including dissenters from the orthodox view.

2. The time is opportune for a comprehensive review of agricultural aims and methods (e.g. encompassing GM, conventional and organic approaches). Ideally, such a review would be at the EU level, but given the current political will to modernise structures and attitudes, there is a clear opportunity for the UK to take the initiative with a national review. We believe that the current crisis in farming lends force and urgency to this recommendation.

3. Close links should be established promptly between the UK's Agriculture and Environment Biotechnology Commission (AEBC) and the Food Standards Agency (FSA), both of which bodies are due to be set up in the near future, to ensure that the FSA benefits effectively from the strategic, including ethical, considerations which are within the remit of the AEBC.

4. The Precautionary Principle (together with a comprehensive ethical analysis, as described above) should form the basis of the approval system for Novel Foods. With respect to applications for the growing of GM crops in the UK, the following elements of the Precautionary Principle are recommended:

- The 'No, unless' principle should be adopted, i.e. the onus of proof of the acceptability of the proposal should lie with the applicant.
- 'Risks' should be taken to refer to impacts on the wide range of issues detailed in the Ethical Matrix and not simply those concerned with safety.
- More consideration should be given to the real-life circumstances in which GM crops might be grown
- Any risks taken should be commensurate with anticipated potential advantages

5. If a GM food is awarded a licence permitting commercial growing in the UK there should be a legal requirement for long-term, independent, rigorous, monitoring of possible adverse effects (e.g. on biodiversity) and obligatory termination of the licence if pre-agreed thresholds are breached.

6. Before any licence to grow GM crops is granted mechanisms should be in place to suspend authorization expeditiously and de-commission the site safely should thresholds be breached.

7. A system of compulsory liability for any adverse effects of GM technology on human health and the environment should be introduced, based on the 'polluter pays' principle.

8. The UK government should ensure that adequate and affordable non-GM food is available to consumers, at least until such time as it became clear that GM food was widely acceptable in society. This will entail increasing government assistance to farmers wishing to convert to organic and other sustainable forms of farming and increasing investment in scientific research in these areas.

9. Given the general dissatisfaction that many, including expert bodies, have expressed with arrangements for the safety assessment of GM foods (and, in particular, the limitations of the concept of 'substantial equivalence') we recommend that more resources are invested in furthering research in this area.

10. Given the general level of public concern over GM foods, we recommend the introduction of a system of compulsory labelling of all products of GM food technology, which is sensitive to consumer demand.

11. There is a moral imperative for Western countries to increase their efforts to relieve hunger and poverty in less developed countries. UK government aid to less developed countries should continue to give primacy to poverty eradication and environmental sustainability, with a particular focus on the needs of the rural poor. Any proposals for the application of GM crops in developing countries should be viewed with extreme caution because of their tendency to cultivate dependency, have adverse social impacts and undermine ecological stability.

12. There is a need for the UK government to introduce legislation to control the imminent spread of functional foods, for which manufacturers may make health claims. Protection of the consumer from overambitious and unverifiable claims is a priority, while recognising that some such products could confer significant health benefits to some people if marketed responsibly and used appropriately.

1. INTRODUCTION

When the working party began its work in July 1998 the GM issue did not have a high profile. The safety of GM foods raised little public concern, since virtually the only GM product available in the UK was a tomato paste - the longer-life properties of which are attributable to an antisense gene, i.e. a normal tomato gene replaced in the genome the wrong way round. Certainly, there was discussion in academic circles about the environmental impacts of growing GM crops, particularly those with genes for herbicide and pesticide resistance, and of the socioeconomic effects of this technology, especially in less developed countries - but public concerns hardly registered on a Richter scale measured in 'BSE units'.

What raised public alarm (though, at first only fitfully) was a brief TV item on 12th August 1998, in which Professor Arpad Pusztai, a senior scientist working at the Rowett Research Institute, Aberdeen, claimed that a type of GM potato fed raw to rats induced adverse effects, including differences in organ size and damage to the immune system. Although concern appeared to fade quickly when it was thought that Prof Pusztai had become confused under questioning, it returned with a vengeance when 20 scientists from throughout Europe issued a statement in his support in February 1999. The ensuing media interest led to high profile campaigns against all GM foods in a number of daily newspapers, which persuaded several supermarket chains to declare their own brand food products free of GM material. Opinion polls revealed that UK consumers were strongly opposed to GM foods, and at least wanted comprehensive labelling to allow the opportunity to avoid them.

A number of reports followed in quick succession, e.g. those of English Nature, the British Medical Association and Christian Aid - all highlighting the environmental risks of growing GM crops, and the importance of maintaining consumer choice. The UK Government's initial attempts to brush criticisms aside became progressively eroded as Ministers were forced to make a series of concessions to stem public anxiety - food labelling, additional safeguards on GM trials, and changes in the composition of ACRE, the government advisory committee on the release of GM organisms into the environment.

It must then have come as a huge relief to the Government and the beleaguered GM industry when a long-awaited report of the Nuffield Council on Bioethics, published in May 1999, appeared to wrest the moral high ground for GM crops. According to the report: "*The moral imperative for making GM crops readily and economically available to developing countries who want them is compelling*".

Working methods

Topics for all reports are decided by the full Council. A working group, chaired by a member of Council, is set up to research and write each report. Each group includes non-Council members, invited to contribute their special skills. Reports are endorsed by the full Council.

Members of the working group for this report were: Prof. Ruth Chadwick (chair: Centre for Professional Ethics, University of Central Lancashire); Dr Peter Lund (School of BioSciences, University of Birmingham); Dr Mairi Levitt (Centre for Professional Ethics, University of Central Lancashire); and Dr Ben Mepham (Centre for Applied Bioethics, University of Nottingham). The working party was assisted by Mr Nicholas Joll (Centre for Professional Ethics, University of Central Lancashire, now at the University of Essex). This analysis of the ethics of novel foods has been based on Mepham's development (the Ethical Matrix) of principles originally formulated for use in the field of medical ethics.

The working group examined published scientific evidence, the legal regulations governing novel foods in the EU and, in particular, the Nuffield Council for Bioethics report 'Genetically modified crops; the ethical and social issues' (1999).

A questionnaire was sent to 43 selected, informed individuals. A summary of the questionnaire responses is given in Appendix 1. The analyses in this report have been informed, inter alia, by these opinions. The names of those responding, together with others from whom helpful advice was received, are listed in Appendix 2. We also acknowledge the help of others who have played a part in the production of this report in Appendix 3.

Although our own deliberations have been conducted on a smaller scale, with far fewer resources at our disposal than Nuffield, the parallel courses of our work will doubtless invite comparison. And given the polarisation of views on this issue (which is apparent from our own questionnaire survey - see Appendix 1) it was almost inevitable that our conclusions would either conform closely to Nuffield or diverge markedly from them. There seems little scope for a 'middle' position because one conclusion leads inevitably to another.

The result of our enquiry is that, while we agree with a number of its specific recommendations, we take issue with the main tenor of the Nuffield report. The logic of their case is not in

question: but it is their premises we find suspect, and the attachment to what we consider a mistaken analysis of the causes and viable solutions of many social and environmental problems related to food and agriculture. Where Nuffield appears to give the green light to GM crops, attaching but minor reservations and conditions to their global use (a position which might be characterised as 'Yes, but'), we are far less sanguine about the likelihood of their ethical deployment. Our position might thus be characterised as 'No, unless':[2] i.e. GM crops should only be used if an overriding case can be made for so doing. We are not convinced that such a case can be made for the vast majority of currently available GM crops, although it is possible that some future applications would pass the test if society were to follow that route. In contrast, we advocate investment in systems of agriculture which promote sustainability, strengthen producer and consumer autonomy and recognise the integrity of the biosphere - all of which could be seriously threatened by the widespread use of genetic modification.

Consequently, we have thought it appropriate to cast our report in the form of 'a response to Nuffield', thereby making explicit a comparison that we believe would inevitably have been made by others. However, it should be noted that our remit differs from that of Nuffield, being wider in some respects and narrower in others. Thus, we include in our analysis novel foods that are not the result of genetic modification but we exclude non-food GM crops. We also exclude novel foods produced by genetic modification of animals, including fish: consideration of these issues will form part of a projected report in this series.

Our terms of reference were to:

- **Consider the scientific and legal basis of novel foods, their claimed advantages and drawbacks**
- **Perform a comprehensive ethical analysis of such foods, drawing on evidence from published literature and other sources (e.g. by analysing the results of a questionnaire sent to a selected group of informed individuals representing a wide spectrum of opinion)**
- **Make recommendations as to the appropriate use and regulation of novel foods, excluding those derived from animal sources, from a UK perspective**

2. NOVEL FOODS: WHAT THEY ARE AND HOW THEY ARE PRODUCED

2.1 Definition of Novel Foods

According to the EC definition (see Box 1) of Novel Foods, there are two reasons for considering a food to be 'novel', viz. it may:

- differ in composition from that previously available, e.g. because of the use of a new manufacturing process.

BOX 1 – DEFINITIONS OF NOVEL FOODS

Novel foods are defined by the EC Novel Foods Regulation 258/97. According to this definition, a food is considered to be novel if:

It has not been used as a food to a significant degree in the EU in the past, and

It is a food or food ingredient which falls into one of the following six categories, viz it:

- *contains or consists of genetically modified organisms (GMOs)*
- *is produced from, but does not contain, GMOs*
- *has a new or intentionally modified molecular structure*
- *consists of or is derived from micro-organisms, fungi, or algae*
- *consists of or is derived from plants or animals (but excluding those which are obtained by traditional practices and have a history of safe food use)*
- *has come from a novel production process which causes changes affecting the nutritional value, metabolism, or presence of undesirable substances.*

*The following definitions are also used in this report:**

Functional food: any modified food or food ingredient that may provide a health benefit beyond the nutrients it contains.

Nutraceutical: any substance that may be considered a food or part of a food and that provides medical or health benefits, including the prevention and/or treatment of disease.

*Parliamentary Office of Science and Technology (1998) 'POSTNote 119'

2 Four categories are used in the Netherlands to characterise decisions on different types of biotechnology: 'Yes' (unconditional approval); Yes, but (the onus is on opponents to make a case for rejection); No, unless (the onus is on proponents to establish a case for acceptance); No (outright rejection). See Advisory Committee on Ethics and Biotechnology (The Netherlands) (1990) Report on Ethics and Biotechnology in Animals. Wageningen: NRLO

- have been produced from a novel source (which could be an animal, a plant, or a microbe) which has not been used for food production in the past. This second category includes foods which consist, totally or in part, of organisms which have been genetically modified (GM), and foods which have been derived from such organisms - even when there is no trace of the modified genes in the final food product.

Novel foods can thus be of quite different kinds (see Box 2). Many processed foods contain GM ingredients (e.g. maize and soya) which confer no nutritional or health advantage on the consumer (although they might prove cheaper than the conventional equivalent), while other GM products, such as long-life tomatoes, are claimed to provide both culinary and cost advantages. At the other extreme are novel foods from non-GM sources which are claimed to confer beneficial effects on consumers' health or reduce their susceptibility to disease (functional foods). Some functional foods are also, and are increasingly likely to be in future, derived from GM sources. For convenience of addressing these issues, we deal below with GM novel food crops first, and then with functional foods.

2.2 Genetic modification

EC Directive 90/220/EEC defines a genetically modified organism (GMO) as any organism that has had its genetic material modified in a way that could not occur through natural processes. Thus, GM is defined in terms of the nature of the process, rather than the product.

To understand the GM process it is necessary to appreciate that all organisms are made up of cells, and every organisms starts out as a single cell which grows and divides repeatedly during its subsequent growth. Each of the many cells of an organism (e.g. the human body contains around 10,000,000,000,000 cells) contains a complete set of all the organism's genes, since they are duplicated in all cells before the cells divide, and one copy is passed on to each of the daughter cells. Genes can be thought of as the molecules that carry information for the properties of living organisms. The information is carried as a code, which is 'read out' by a complex process in every cell to produce proteins which determine many of the properties of cells, and hence of the whole organism.

Advances in the last forty years have allowed individual genes to be isolated, manipulated in various ways, and introduced into other organisms in such a way that they become a part of the total genetic make-up of that organism. Because all organisms use essentially the same system for reading and interpreting the genetic information, the same gene can be made to function in almost any organism, often giving it new properties. Thus, many traditional barriers between species have disappeared, at least as far as the transfer of single genes is concerned.

To produce a GMO, the novel gene has to be introduced into a single cell of the organism, and that cell in turn must be able to grow into a complete organism. Under appropriate laboratory conditions, many plants can be regenerated from single cells. As the cell grows, divides, and makes copies of its genetic material to pass on to the duplicated cells produced by cell division, the new gene will also be copied. Eventually, the gene will be present in all the cells of the organism, which is then also referred to as a 'transgenic organism'. Moreover, it will also be passed on to some or all of its progeny.

There are no theoretical reasons why genes from any organism cannot be introduced into any other organism; thus it is possible to make GM plants that contain human genes (and this has indeed been done). Genes can also be isolated from an organism, changed 'in the test tube' to alter the properties of the substance that they code for, and reintroduced into the same organism. It is also possible to manipulate genes so that they can prevent other specified genes already present in an organism from having their usual effect. This is the basis of the slow ripening GM tomatoes, used in tomato paste, which were marketed until recently in Safeway and Sainsbury stores. In all cases, the resulting changes could not have been brought about by any other known method.

2.3 The aims of genetic modification of food

Companies produce GM foods to try to increase their share of the food market, lower food production costs, favour sales of other products which they produce (e.g. a herbicide), or some combination of all three. A GM food may be marketed by promoting its novelty, with claims that the change will directly benefit the consumer. Alternatively, the novelty of the food may not be advertised at all, the benefit to the company being purely in terms of savings or other benefits during some part of the production process, none or only some of which might be passed on to consumers.

Foods which are claimed to be 'substantially equivalent' to those they replace, but which are classed as novel because they come from new sources, include many of the products of GM crops that have appeared in processed food in the UK, and which have provoked such controversy in recent months. The best known example is GM soya, derivatives of which are present in a wide variety of processed foods. The chemical compositions of the various derivatives are claimed to be identical with equivalent products from non-GM soya.

BOX 2 - NOVEL FOODS LICENSED FOR USE IN THE UK

The only GM foods which have been licensed for use in the UK to date are:

- *Chymosin enzymes from GM source organisms: used in the production of 'vegetarian' cheeses*
- *GM tomato paste, produced from slower ripening fruit*
- *GM herbicide tolerant soya beans; used in a wide range of processed foods*
- *GM maize; used in a wide range of processed foods*

Non-GM novel foods include:

- *Green tea extract: from the unfermented, dried leaves of the tea plant Camellia sinensis, used in artificial sweeteners*
- *Lactobacillus GG: several strains are used as starter cultures in the production of fermented milk products*

Source: Advisory Committee for Novel Foods and Processes (1999) Brochure.

2.4 *Categories of potential GM crops*

GM technology has developed very rapidly in the last twenty years, largely due to the fact that the examples introduced to date are almost entirely traits governed by a single gene, such as herbicide resistance or insecticide production. Photographic images of plants containing the Bt gene (coding for *Bacillus thuringiensis* toxin) surviving an insect attack that would reduce their non-transgenic parents to leafless skeletons give the impression that it is possible to manipulate plants in any way we choose. However, genes regulating key agronomic traits that are needed for improved productivity are often more complex.

Broadly, GM is focused on four types of trait, viz:

2.4.1 Traits responsible for resistance to 'biotic stresses', viz. infection by viruses, fungi, insects, competition from weeds etc.

This is the type for which most success, to date, has been reported. Attack by pests causes very significant losses in crop productivity around the world, and the extensive use of chemicals to prevent this in the West is enormously damaging to the natural environment. However, as discussed in this report, the use of GM crops expressing genes for insecticide production and herbicide resistance is raising a number of serious questions about adverse environmental impacts.

2.4.2 Traits that directly affect yield characteristics of the plant, e.g. height, time of flowering, number of seeds

Generally speaking, these traits are controlled at the genetic level by complex interactions between several genes, often referred to as 'polygenes' or QTLs (quantitative trait loci). It is much more difficult to map and isolate these genes than it is to study single gene traits, and to date there have been no reports of the successful transfer from one plant species to another of genes involved in QTLs, that have had a significant effects on any of the yield characteristics of the plant. Indeed, the nature of these genes and their effects is currently poorly understood. So it is not yet clear whether the transfer of an individual QTL from one plant species to another will have any useful affect on the plant's performance, since it may be part of a complex network of interacting genes that would all have to be transferred simultaneously - technically a very difficult proposition.

2.4.3 Traits responsible for resistance to 'abiotic stresses', viz. extremes of temperature, drought, high salinity

These are often the traits most touted by strong proponents of GM, particularly when arguing for the benefits to less developed countries. Large parts of the Earth's land surface are uncultivable because they are too dry, too wet, too hot, too salty, or the soils are too poor or contain toxic materials (including much land that was fertile before being over-grazed or over-cultivated in the past). It is often claimed that GM plants will be able to overcome these stresses. For example, freezing tolerance can be enhanced by genetically manipulating one gene that has an effect on the way several other genes are expressed.[3] On the face of it, this would seem to have significant potential because crop losses due to late frosts can be a serious problem in some climates. However, the process has so far only worked in a 'demonstration' plant that already shows some freezing tolerance; it is not clear that the same strategy will work in many crops which have no freezing

3 JaglooOttosen K R et al (1998) Science 280, 104-06

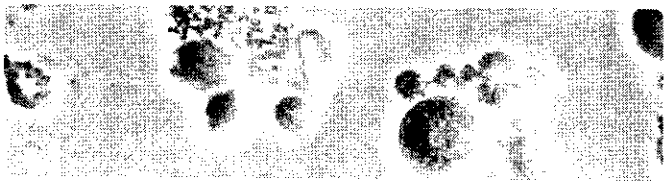
tolerance (such as citrus fruits). Moreover, many abiotic stress resistances are governed by QTLs, with the drawbacks mentioned (2.4.2).

2.4.4 Traits that are entirely novel to a crop, e.g. the ability to fix nitrogen

These are the most ambitious, and, technically, the hardest to achieve. Nitrogen in the soil is a key factor affecting plant productivity, and the only plants that can convert atmospheric nitrogen into a form that can be utilised by other organisms are those using symbiotic bacteria in nodules on their roots - the legumes (such as peas, beans, and clover). This is why these crops figure so prominently in crop rotation regimes. Without any other means of getting nitrogen into soils, fertilisers are used, which are expensive to produce and can have negative environmental impacts.

Given that the genetics of nitrogen fixation in bacteria are fairly well understood, cannot the genes responsible simply be transferred into plants like rice and wheat? Consideration of this issue illustrates a misconception that has led to some exaggerated claims of what GM is capable of achieving. Many genes only exert their effects in the context of all the other genes in the organism, which in part determine the form that the organism takes. Most of the properties of any organism are best considered and understood at the level of the whole organism, rather than the cells that make it up. For example, a key protein in the fixation of nitrogen is poisoned by oxygen. This is not a problem in root nodules, which have evolved mechanisms to exclude oxygen, but it would be a major problem in plant cells, where the level of oxygen can be very high.

The more complex the trait being engineered, the more likely it is that its expression is the consequence of many genes acting together which could not be transferred *en masse* to a new organism and have their effect there. The adoption of practices which are based on the assumption that all properties of organisms can be ascribed to the additive function of single genes, and that all that is required to change the properties is to manipulate these genes, has sometimes been called 'genetic reductionism'. Naïve belief in this view leads to greatly exaggerated claims of the powers of GM, and also raises false hopes in implying that complex problems will necessarily have simple solutions.



2.5 Functional foods

The science of nutrition has latterly undergone a major change of emphasis. Nutrition used to be about identifying and rectifying nutrient deficiencies, as though, once defined, the perfect diet could be expressed in a simple formula. Of course, it has long been believed that certain foods are particularly 'good for you'. How many generations of children have been encouraged to eat up their greens 'to purify your blood' and their fish 'to make you brainy'? The validity of such claims is somewhat doubtful (and probably more related to encouraging consumption of food which children find unpalatable) but, in principle, different diets are likely to have significantly different effects on health. For example, high consumption of fruit and vegetables is acknowledged to reduce the risk of heart disease and certain cancers, while high levels of meat consumption are correlated with an increased incidence of cancer.

Now, however, nutrition, at least in Western societies, is becoming increasingly concerned with promoting health and preventing chronic disease. Diet is recognised as a major contributory cause of cardiovascular disease, cancer, obesity, diabetes and dental caries. Consequently, dietary restriction and supplementation are widely believed to be beneficial in counteracting predispositions to disease and enhancing performance, both physically and mentally. In short, the ideal diet is no longer to be defined simplistically but is subject to infinite qualitative and quantitative variation, depending on individual choice and proclivity.

The recent UK government White Paper 'Saving Lives: Our Healthier Nation' set targets for the year 2010 in four main areas, of which two were related to food:

- Heart disease: the target is to reduce the death rate from coronary heart disease and stroke and related diseases in people under 75 years by at least 40%

- Cancer: the target is to reduce the death rate from cancer in people under 75 years by at least 20%.[4]

It is against this background that the food industry has begun to take an interest in functional foods and nutraceuticals (for definitions, see Box 1). These are novel foods which differ in composition from normal foods and are also claimed to improve health, although no legal definitions have yet been agreed. An example is a type of margarine, recently introduced into the UK, which has been shown in some, although not all, independent studies to lower blood cholesterol levels.[5] Given that all foods have the ability to confer some health benefit, they might all be regarded as 'functional' to some degree, so the use of the terms

4 Department of Health (1999) Saving Lives: Our Healthier Nation. London: Stationery Office
5 See Medical Sciences Bulletin (1998) 253 (internet journal)

functional food and nutraceutical might be thought more a matter of marketing than of strict definition. However, they are certainly novel in that they contain different ingredients or different amounts of ingredients to those normally present in our diet.

2.6 Future developments

The combination of the concept of functional foods and the techniques of GM point to some astonishing future possibilities, that could lead to a complete revision of the way in which food is regarded and the role it might play in maintaining a healthy lifestyle. For example, plants can be genetically modified to produce vaccines and antibodies, including antibodies which have been successfully used to protect experimental animals against non-Hodgkin's lymphoma,[6] a form of cancer which is usually fatal. So if this technology proved effective in clinical trials, GM foods might replace some forms of medicine for the treatment or prevention of diseases.

Such technical possibilities raise a host of ethical questions about benefits, risks, deception, fairness, resource allocation and the value of more holistic strategies for promoting a healthy lifestyle. Assessing the ethical impacts of such potential developments may prove to be one of the most challenging tasks facing us in the early years of the next century.

2.7 UK regulation of novel foods

In the UK, the government agency charged with assessing the safety of novel foods is the Advisory Committee for Novel Foods and Processes (ACNFP). Other committees whose advice is sought are the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) and the Food Advisory Committee (FAC). If a GM crop is to be grown in the UK, applications have also to be assessed by the Advisory Committee on Releases to the Environment (ACRE).

The outline assessment procedures for novel foods are laid down in Regulation (EC) 258/97. Safety assessment follows "a comparative approach set out by the EC guidelines", in which, "wherever possible, the novel food is compared with an existing counterpart, which it may replace in the diet". According to this procedure, identified differences undergo a detailed examination to establish whether the novel food is as safe as its existing counterpart.

The concept of 'substantial equivalence' (SE), was introduced with particular reference to products of modern biotechnology, and "codifies the idea that if a food or food ingredient ... can be demonstrated to be essentially equivalent in composition to an existing food or food ingredient then it can be considered ... as safe as the conventional equivalent. The levels and variation for characteristics in the novel food must be within the natural range of variation for those characteristics considered in the comparator and must be based upon an appropriate analysis of data". [7]

In establishing the need for toxicological data, three scenarios are considered:

- SE to a traditional food is deemed to be established, so no further testing is required
- SE to a traditional food is deemed to be established except for a single or a few specific traits, in which case further safety assessment should focus specifically on these traits
- Neither partial nor total SE can be established, in which case the 'wholesomeness' of the novel food has to be assessed using a 'combined nutritional-toxicological' approach, which considers factors such as its potential mutagenic, teratogenic and allergenic properties .

"If SE ... cannot be established the wholesomeness assessment has to take into account not only the knowledge of the identity, chemical structure and physico-chemical properties of the novel food but also aspects such as source, composition, potential intake based on the proposed use in the general diet, the potential exposure of particularly vulnerable population groups; and likely effects of processing. The greater the predicted dietary exposure the more extensive the required toxicological testing programme will have to be." [8]

Functional foods merit further consideration here because of their claimed heath-promoting properties. Currently, Japan has the largest market for functional foods, having licensed over 100 different products through their regulatory system. With government permission, manufacturers are allowed to make agreed claims concerning safety, substantiation of health advantages etc. [9] However, EC legislation prohibits medical claims, i.e. that a food has the property of preventing, treating or curing a disease - except in certain specific circumstances. Claims have thus to be made in only very general terms (such as 'Eat X for a healthy diet') or in terms which describe the nature of the product but not alleged medical benefits (such as 'Y has low cholesterol').

Following the issuing on draft guidelines by the UK Food Advisory Committee in 1996, a Joint Health Claims Initiative (involving representatives of the Food and Drink Federation, the

6 Alison A et al (1999) Proc Nat Acad Sci USA 96: 703-708.
7 ACNFP Annual Report (1999). London: Stationery Office, p.2
8 Ministry of Agriculture, Fisheries and Food (MAFF) (1999) Assessment of Novel Foods. p.5
9 Parliamentary Office of Science and Technology (1998) Health claims and foods.(POSTNote 19). London

National Food Alliance and the Local Authority Body on Food Trading Standards) was set up in 1997 to clarify the existing regulatory position. Their (voluntary) draft Code refers to health claims on labelling, advertising and promotion of all foods marketed to the general public.[10] Two main types of claim are distinguished:

- *Generic claims* - based on well-established evidence in the scientific literature, for which no further substantiation would be required

- *Innovative claims* - requiring substantiation (e.g. providing detailed evidence of food safety and specific physiological effects)

It seems likely that there will increasing demand for such products in future, and that exploitation of technological advances such as GM will increase the pressure on governments to introduce appropriate regulatory legislation.

2.8 Intrinsic objections to GM food

There is some evidence to suggest that objections to GM food products are likely to focus on specific applications rather than on the GM process per se.[11] Different attitudes to different products may be explained by the organisms involved or the type of benefit and identity of the perceived beneficiary of a particular technology. The view that there is nothing 'in principle' objectionable about genetic engineering is compatible with a view that regards GM just as a more sophisticated mechanism of traditional plant breeding processes. A different picture emerges from consumer surveys in Europe, which have found a contrast in types of concern between those focusing on safety and those expressing opposition 'in principle', arising from deep anxieties about such things as 'tampering with nature.' In the US, on the other hand, there appears to be a wider consensus that GM crops are inherently safe, along with a lack of concern over interfering with nature. It has been suggested that this arises from a more 'instrumental' attitude to food in the USA.

What grounds might there might be for an 'in principle' opposition to GM food? If this opposition is expressed as concern that it is 'unnatural', then the problem arises as to how to define 'natural'. If it is taken to mean anything that occurs without human agency, then effectively all of agriculture is unnatural, in that there are hardly any foodstuffs, and certainly no staples, that have not been extensively modified by conventional plant breeding for many millennia. For example, familiar crops such as wheat and rice are now so dissimilar from their distant wild forbears, from which they have been derived by a slow process of both deliberate and unconscious selection, that it is not possible to determine precisely which wild plants they are descended from. If 'natural' is taken to refer only to what takes place in the natural environment - as opposed to in the laboratory - then a preference for the natural would rule out plants currently produced by method such as micropropagation, (e.g. bananas). Where preferences for 'the natural' exist they may turn out to depend on constructions of 'the natural' that are matters of degree.

The 'in principle' opposition, however, may rest on a deeper unease about the very process of directly manipulating something as fundamental as the genes that determine the nature of the organism, a concern that this represents hubris on the part of the scientists who develop the technology, or an unacceptable increase in the human control of the natural world. This frequently finds expression in the 'playing God' objection, although this may itself be interpreted as a warning of the dire consequences that may ensue as a result of overstepping natural boundaries.[12] In this way the 'in principle' opposition slides into a fear about unpleasant and (typically) unforeseeable consequences.

A further type of 'in principle' opposition, however, (acknowledged by Nuffield) arises from the Heideggerian tradition, which offers a line of argument that even if GM food can be shown to be overwhelmingly safe, and even if regional and world economics and politics are not too adversely affected, plant biotechnology may still be part of a process that impoverishes our experience of the world. The type of worldview that conceives of, say, plants instrumentally, apart from their wider significance in the world, is regarded as narrow and thereby impoverishing.

None of these 'in principle' objections is conclusive. There is a difference between acknowledging an intrinsic objection and holding that it should be absolute, overriding other values. The important question for policy is how to acknowledge and weigh them against other considerations. The next section proposes one way of incorporating some of these concerns alongside arguments about safety. Such considerations take into account preferences about the kind of world in which we want to live, and the preference for what is, at least, perceived as more 'natural', even if there is no absolute boundary that can be drawn.

10 See note 9
11 Frewer, L. et al. (1997) Agriculture and Human Values 14: 67-79
12 Chadwick R (1989) Cogito 3, 186-193.

3. AN ETHICAL APPROACH TO BIOTECHNOLOGY ASSESSMENT

3.1 Background

Currently, prospective technologies are routinely subjected to assessment procedures to ensure that they deliver the claimed benefits reliably and without significant risks to people, animals and the environment Once these criteria have been satisfied, market forces tend to be regarded as the appropriate means for addressing other issues of public concern. While in theory (e.g. in a society where there was a high level of public awareness and trust) the free market might be a satisfactory way of ensuring consumer choice and protection, many aspects of modern-day food production present a profound challenge to this assumption. Questions relating to the origins of our food, its means of production, dependence on problematical technologies, and impacts on the welfare of consumers, animals and the environment, cannot be assessed simply on the basis of economics and technology, not least because animals and the environment cannot express their interests as 'stakeholders'. A satisfactory form of ethical assessment needs to take account of these issues.

A sound starting point for deliberation is to outline principles of the common morality or 'common-sense ethics', which most reasonable people share. One problem with such a claim is that it depends rather critically on how you define 'reasonable'. Different cultures might see things differently (human autonomy, women's rights, animal rights) yet still be considered rational, if not reasonable. Nevertheless, despite multiculturalism and pluralism, the pursuit of democracy, which few in our culture would challenge, makes certain assumptions that conform to the idea of the common morality.

These assumptions have been described by the American medical ethicists, Tom Beauchamp and James Childress, who identify four principles, namely *prima facie* respect for ***beneficence***, ***nonmaleficence***, ***autonomy*** and ***justice***.[13]
In a medical context:
Beneficence refers to 'doing good'; i.e. the duty to help the patient by effecting a cure or relieving suffering.
Nonmaleficence refers to 'doing no harm' (the ancient Hippocratic Oath) and this applies, for example, to avoiding procedures which might be undertaken primarily to advance knowledge or skills, rather than for the good of the patient.
Autonomy concerns respect for the patient as a person, and not just as a 'case'.
Justice is interpreted as 'fairness', e.g. showing no favouritism or sexual, racial or age preference.

This, so-called, 'principled approach' to medical ethics seeks to assist health professionals in addressing many of the dilemmas with which they are constantly faced. The use of the principles does not determine the outcome but it does ensure that attention is paid to a range of ethically relevant issues, that there is a consistency of approach towards patients, and that the decisions made are explicit and can be verified (or challenged). The principles are based on established ethical theories (even though most people are not aware of them) which commonly feature in perceptions of 'right action' (see Box 3).

In adapting this approach to agricultural and food biotechnologies, Mepham[14] noted that the following are valuable with respect both to medicine and food production.

- the assumption of a common morality
- a principled approach which is based on established ethical theory
- the characteristics of rationality, transparency and consistency.

There are, however, several important differences between medical ethics and food ethics. Thus, for the latter:
- there are more 'interest groups' (e.g. consumers, farmers, animals and the living environment)
- the ethical analysis needs to impact on public policy decisions (and not simply, as may often be the case, *ad hominem* in the surgery)
- to be of use in democratic, publicly-accessible policy making, the terminology needs to be as simple and user-friendly as possible (or, at least, comprehensible to the committed non-expert)

13 Beauchamp T L and Childress J F (1994) Principles of Biomedical Ethics, 4th edition. New York and Oxford: Oxford University Press
14 Mepham B (1996) Ethical analysis of food biotechnologies: an evaluative framework. In 'Food Ethics' ed. B. Mepham. London: Routledge, pp 101-119

3.2 The Ethical Matrix

In this report, we propose to analyse the issues raised by applying the ethical principles described above to the interests of three groups, viz:

- **The Biota:** i.e. the living environment.
- **Producers:** i.e. farmers, in both developed and developing countries
- **Consumers:** in this case, those who consume novel foods.

Respect for these three groups is considered in relation to the principles of ethics described, namely autonomy, justice and, here, wellbeing (the latter combining, for simplicity, the principles of beneficence and nonmaleficence - which are often closely and reciprocally interrelated). (If we had been considering novel animal products, 'treated animals' would have constituted a fourth 'interest group'.)

Because the three principles and three interest groups interact, the nine resulting ethical impacts can be represented in the form of a table (the Ethical Matrix),[15] which aims to facilitate analysis by imposing a rational structure (see Table 1). But it would be a mistake to imagine that the Matrix can resolve complex ethical issues simply by consigning their elements to the separate 'cells'.

In the Matrix, the way in which the three principles impact on the interests of the various groups affected by agricultural and food technologies is expressed in terms which are intended to be familiar but are at the same time authentic from an ethical perspective; e.g. respect for consumer autonomy (effectively 'choice') may translate into a requirement for food labelling, that for the consumer wellbeing as 'food safety'. The 'biota' are defined as 'animal, plant and microbial life', i.e. the wildlife which constitute the living environment: (it is assumed that geological formations per se are not ethically relevant, although effects on them may well be ethically relevant for humans).

At its simplest, the Matrix is merely a check-list of concerns, which happen to be based on ethical theory. But it can be much more e.g. by serving as a means of promoting public awareness and as a stimulus to ethical deliberation. It is, of course, impossible to discuss the full significance of this approach here, any more than it would be possible to give a satisfactory account of, say, biochemistry, in a couple of pages. Since the Matrix per se has no substantive output, its value can only be measured in terms of its 'usefulness'.

However, it is important to note that :

- *the Matrix is not prescriptive: even if one were to assign scores to different 'cells' (e.g. a food technology might improve food safety and thus score +3 in that cell, but reduce choice, leading to a score of -2 in that cell), the fact that individuals weigh the cells differently precludes a definitive decision on ethical acceptability.*

- *it is probable that no form of biotechnology or system of food production could afford equal respect to all the ethical principles, and hence some may need to be overridden by others, or respect for some only partially discharged.*

- *the Matrix can only compare two situations (usually, conditions with and without a proposed technology) but if the conditions without the proposed technology represent the status quo, this might unduly limit the options for*

Respect for	WELLBEING (Health & Welfare)	AUTONOMY (Freedom/choice)	JUSTICE (Fairness)
THE BIOTA*	Conservation of the biota	Maintenance of biodiversity	Sustainability of biotic populations
PRODUCERS	Adequate income & working conditions	Freedom to adopt or not to adopt	Fair treatment in trade and law
CONSUMERS	Availability of safe food	Respect for consumer choice (e.g. labelling)	Universal affordability of food

Table 1

The Ethical Matrix showing, in nine individual cells, the interpretation of respect for the three principles of wellbeing, autonomy and justice in terms appropriate to the interests of (in this instance) farmers, consumers, and the biota (animal and plant life of the natural environment). *This term is explained briefly in the text.

15 See note 14

ethical action: alternative scenarios need to be included within the analysis.

- *the Matrix is designed to facilitate decision-making by making explicit the relevant ethical concerns, encouraging ethical reflection and discussion.*

It is interesting that the Nuffield report was guided by three similar ethical principles viz "general human welfare, the maintenance of human rights and the principle of justice" (Nuffield, page 3), although we have interpreted them more broadly.

BOX 3 - BACKGROUND ETHICAL THEORY

According to the approach adopted here, respect for ***wellbeing*** *corresponds to issues prominent in utilitarian theory, which characteristically employs a form of cost/benefit analysis to decide on 'right action'. Most famously articulated in the eighteenth and nineteenth centuries by Jeremy Bentham and John Stuart Mill, it can be epitomised as 'The greatest good for the greatest number'. While this might seem a worthy objective, naive forms of utilitarianism suffer from several defects e.g.:*

- *they depend on predictions of outcome (which may be wrong) and (fallible) assessments of who or what counts in the cost/benefit analyses*
- *they can be held to justify gross inequality (as long as the majority 'are happy') or even crime (stolen money distributed to the needy)*
- *goods and harms are often incommensurable (how can we weigh the safety of a hair shampoo against the suffering of animals used to test it?)*

Respect for ***autonomy*** *corresponds to the notion of 'rights' advanced in the eighteenth century by Immanuel Kant, which appeals to our responsibilities and duties to 'treat others as ends in themselves': in essence, the Golden Rule: 'Do as you would be done by'. For Kant, ethics was about respecting others as individuals, not calculating costs and benefits (i.e. in contrast to utilitarianism, irrespective of outcome).*

- *A major defect of this approach taken in isolation is that there is no rule by which to decide how to prioritise duties, e.g. the duties to protect others from harm and to tell the truth - if, as may happen, telling the truth is a cause of harm.*

Respect for ***justice*** *corresponds to Rawls' notion of 'justice as fairness'. For Rawls (a contemporary US philosopher):*

> *"Justice is the first virtue of social institutions, as truth is of systems of thought. A theory, however elegant and economical, must be rejected or revised if it is untrue; likewise laws and institutions, no matter how efficient or well arranged, must be reformed or abolished if they are unjust".**

- *However, there is a problem in defining what fairness means: e.g. does it mean that goods should be distributed according to need, or ability, or effort?*

In practice, all these theories are likely to contribute, to varying degrees, to people's attitudes on what should be done in specific circumstances. It seems unlikely that anyone could consistently act as an out-and-out utilitarian; or as an out-and-out Kantian. Instead, each of us blends these theories (consciously or unconsciously) with intuitive responses and cultural influences to achieve what has been termed a 'reflective equilibrium'.

*Rawls J (1972) A Theory of Justice. Oxford: Oxford University Press

3.3 Application of the Ethical Matrix to Novel Foods

The aim in the following sections is to examine novel foods used, or proposed for use, in the light of the principles defined in the Ethical Matrix. We discuss GM foods first and then functional foods. In theory, the consequences of using such novel foods could respect, infringe or have no impact on each of the ethical principles. Our approach is to report ethical impacts on the separate interest groups (biota, producers and consumers) as objectively as possible.

Within the space available, it is only possible to perform summary analyses; a process which is, however, facilitated by the recent publication of several reports on the subject, and particularly, that of the Nuffield Council on Bioethics. It should be appreciated that the authenticity of the analyses is dependent on a rigour that cannot be demonstrated here: readers wishing to examine the primary data are referred to the the reports cited. We structure the analysis with reference to the principles identified in the Ethical Matrix, which are denoted by ***bold italics*** type.

It should also be noted that much of the analysis consists of a process of challenging assertions made by proponents of novel foods. This does not represent a bias in our approach but is simply a consequence of the inevitable structure of the debate. Claims for technologies are typically expansive and lacking in detail: they assert that 'herbicide use will be reduced' or that 'tomatoes will ripen more slowly', both without significant adverse effects. Those seeking to test such claims must necessarily look for specific instances where the claim might be falsified. This is a much more detailed process, which takes up more space than simple affirmative statements.

We then conclude our analyses with ethical evaluations, which form the basis of a number of our subsequent recommendations. These evaluations represent the outcome of our 'weighing' of the impacts of the cells of the Matrix, coupled with appeal to the Precautionary Principle (see 6.1) when the available evidence reveals significant uncertainties. We believe that our ethical assessments of the evidence, in the manner presented in the Matrix, will find general support, although few people will have considered the issues in the terms used here. But even if there is disagreement over the ethical evaluations, the proposed framework may nevertheless facilitate fruitful dialogue.

4. GM FOOD CROPS

In referring to the Nuffield Council on Bioethics report on 'Genetically modified crops: the ethical and social issues' (hereafter, 'Nuffield') direct quotations are in "*italics*" and the paragraphs cited are shown in italicised brackets and preceded by '*N*', e.g. *(N 8.8)*. Cross-referencing to other paragraphs in this report is in regular type, e.g. (4.2.1).

4.1 THE BIOTA

Environmental issues are fundamental, affecting farming practices in the short term, the appearance of the landscape in the medium term, and, conceivably, the viability of the biosphere in the longer term. Consequently, our analysis begins with a consideration of impacts of GM crops on the biota.

4.1.1 Background

Nuffield appears to see no serious problems in terms of the environmental impacts of GM crops. Thus, "*We do not advocate a moratorium on ... field trials, or limited release into the environment ... the next step should be to allow some commercial planting of the most promising GM crops ...*" *(N 8.63)*. But this demonstrates a degree of optimism not shared by some distinguished geneticists, environmentalists and medical specialists.

In a BBC television programme broadcast in April, 1999, Professor Steve Jones, leading geneticist and Reith Lecturer, compared GM crops with penicillin: "If you had said in the 1940s that penicillin would be completely useless in parts of the world within 50 years, people would have thought you were mad. But you would have been right. Evolution picked up a gene and changed it, and now the bacteria are resistant to penicillin. We are doing more or less the same with genetically modified plants. Those genes are going to get out into other plants. Everybody knows that. And we have no idea what is going to happen." Considering the possibility of the escape of a gene conferring resistance against insects, Jones proceeded: "Suddenly we have no insects. With no insects you have no ecology, no ecosystem, no pollinators, no flowers, God knows what. ....A tiny accident, one gene leaking out can have massive consequences."[16]

Baroness Young, Chair of English Nature, is similarly alarmed. She claimed: "Intensive agriculture over the last 30 years has decimated our wildlife. This new [GM] technology has the capacity for even greater damage"[17], while the Director of English Nature, Dr Brian Johnson warned that "some of the country's

16 Jones S (1999) in BBC2 programme Leviathan (14.4.99)
17 Young B (1999) in Independent on Sunday (14.2.99)

most treasured birds and wildlife could be wiped out if genetically modified crops are grown without more testing. .... the skylark, the linnet and the corn bunting, which all live on farmland could be at particular risk".[18]

Such concerns are echoed by the British Medical Association, whose recent report states that "..any conclusion upon the safety of introducing genetically modified materials into the UK is premature as there is insufficient evidence to inform the decision making process at present", and which recommends a moratorium on the commercial planting of GM crops in the UK "until there is a scientific consensus ... about the potential long-term environmental effects."[19]

4.1.2 Ethical analysis

The claimed benefits of GM crops are perhaps epitomised by one form of GM maize, which is present in food ingredients used for brewing, bakery products, salad dressings, snack foods and margarines. The maize contains three transgenes, *viz.* for:
i) herbicide resistance, viz to glufosinate ammonium
ii) pest resistance
iii) ampicillin (antibiotic) resistance, i.e. a marker.[20]
Thus, farmers growing this herbicide-resistant crop (HRC) can spray it with the herbicide, which kills competing weeds but not the crop itself; and because the plants contain the Bt toxin (see 4.1.2.2), losses from infestation with European corn borer will also be reduced.

Our ethical analysis demands that we examine these claims in the light of impacts on the three ethical principles defined in the Ethical Matrix, viz. ***conservation***, ***biodiversity*** and ***sustainability***.

4.1.2.1 In terms of ***conservation***, it is claimed that herbicide resistant crops (HRCs) will lead to reduced overall use of herbicides, which will be beneficial to the environment. Nuffield cites several examples of reports supporting this claim *(N 6.20)*. In contrast, a recent report from the United States Department of Agriculture found that in two thirds of the cases examined, use of GM crops did not lead to decreased herbicide or insecticide use; e.g. use on GM herbicide-resistant cotton was no different from use on non-GM cotton.[21]

While, in the short term, there might be reduced need for spraying the crop with pesticides and herbicides, thus reducing adverse effects on biota, it is possible that subsequently several problems might arise. Thus, a recent Royal Society report acknowledged that:

- HRCs may be transformed into weeds
- HRC 'volunteers' may act as reservoirs of pests and diseases, undermining the principles of crop rotation.[22]

There is also concern that genes from crop plants may pass into wild relatives, possibly leading to the production of weeds which will no longer be sensitive to herbicides. That such gene flow can and does occur is no longer in doubt;[23] the question, as yet unresolved, is what effect it will have. Recent studies show that once a gene for herbicide resistance has moved from a crop plant into a wild one, it may become stable and not reduce the fertility of the wild plant. The fact that this has been demonstrated in a plant that can cross with oil seed rape and is a serious weed of twenty crops in over fifty countries[24] illustrates the potential problems that may arise.

The use of 'gene stacking' - introducing several genes conferring resistance to different herbicides or different pathogens - may make the consequences of such an event more serious.[25] Even where no native species related to a particular crop exists in the country where it is planted, the possibility of unexpected gene transfer occurring elsewhere cannot be ruled out - e.g. through the accidental transport of seeds. A well known botanical precedent is the formation of the highly invasive cord-grass *Spartina townsendii*, which arose as a hybrid between European and American species, probably after inadvertent transfer in ships' ballast.

Moreover, it should be recognised that it is at least possible that herbicide use will be increased (a clear commercial objective) because farmers will be able to spray them more often and more liberally without risk to the crop. Clearly, much will depend on economic factors, such as the relative costs of herbicide, seed, labour and the returns on yield increases.

In any event, the herbicides to which resistance is being engineered are known to have several adverse effects. Glufosinate, a broad-spectrum weedkiller, is highly soluble and "under certain conditions significant run-off or leaching could occur, leading to contamination of ground or surface water."[26] According to the US Fish and Wildlife Service, glyphosate, another herbicide commonly used with GM crops, such as soya, endangers 74 plant species.[27] Those who advocate use of HRCs claim that the alternative, use of more and a greater variety of herbicides, has considerably worse environmental impacts. However, an important consideration is the nature of alternative systems of crop production: the currently dominant intensive systems are not the only viable options (see 4.2.2.2)

18 Vidal J (1999) in The Guardian (8.7.98) p.11.
19 British Medical Association (1999) The impact of genetic modification on agriculture, food and health. London, p.12
20 Institute of Grocery Distribution (1998) Genetically modified foods: maize (information leaflet)
21 Kleiner K (1999) New Scientist 10.7.99, p.23
22 Royal Society (1998) Genetically modified plants for food use. London, p.10
23 Chevre AM et al (1998) Theoretical and Applied Genetics 97, 90-98
24 Snow AA et al (1999) Molecular Ecology 8, 605-615
25 National Biological Impact Assessment Program, USA (1999) Workshop on ecological effects of pest resistance genes in managed ecosystems (March, 1999) http://nbiap.biochem.vt.edu/
26 MAFF (1991) Advisory Committee on Pesticides Annual Report. London: HMSO.
27 Cox C (1995) J. Pesticide Reform 15, 4

4.1.2.2 With respect to ***biodiversity***, the recent Royal Society report (1998) states: "The major adverse effect of HRCs is the more effective destruction of weeds which is likely to reduce the availability of habitats for various insects and invertebrates".[28]

The same effect may result from the incorporation of Bt genes enabling the crop to kill infecting insects, by causing production of an 'internal insecticide'. The Bt toxin, a naturally produced insecticide, confers protection from attack by the European corn borer. However, while normal genes code for prototoxins, which are generally inactive and are only activated in the larval gut, the GM forms of Bt toxin are fully active, and non-target species are also likely to be affected. There is certainly evidence of the potential for harm to non-target species from use of GM crops expressing genes for insecticides. For example:

- "larvae of the monarch butterfly reared on milkweed dusted with pollen from GM corn expressing Bt toxin ate less, grew more slowly and suffered higher mortality than larvae reared on leaves dusted with untransformed corn pollen."[29]

- Laboratory studies in which green lacewing larvae were fed *Bt* toxin from GM organisms showed that the immature mortality rate was significantly higher than in the untreated control group.[30]

- When aphids fed on GM potatoes expressing snowdrop lectin (another insect toxin) were fed to ladybirds the females lived only half as long and produced more than double the number of unhatched eggs compared with ladybirds fed normal aphids.[31]

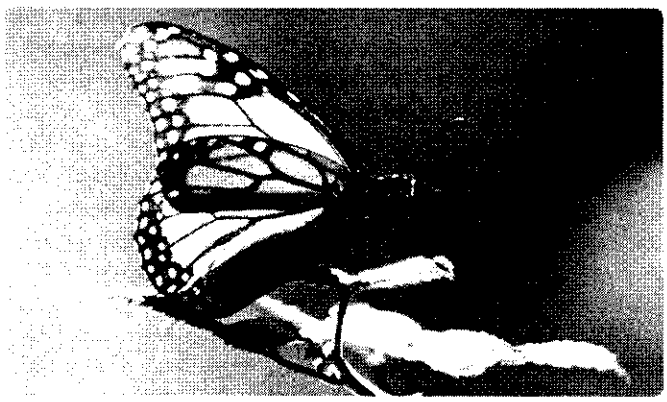
Another critical issue is the possible increase in the evolution of resistant strains of corn borer, since "there is no reason to assume that this problem (encountered with conventional insecticides) will not be repeated for GM crops".[32] Nuffield makes little of the problem, suggesting that "*Bt insecticides used as sprays will also have that effect*" and that "*Breeding insect resistance into crops by conventional means will also encourage the development of immunities in insect pests*" *(N 8.8)*. However, no studies have been reported on the comparative rate of evolution in the field of *Bt* resistance in insects exposed to *Bt toxin* in GM plants or as an occasional spray. Given that *Bt* crops now account for about one third of all GM crops planted world wide, the probability of *Bt* resistance arising and causing loss of produce would seem to be significant, and there is still no industry-agreed standard management plan to deal with this problem.[33] According to the World Bank, insects can adapt within "one or two years" and where major crops are modified to produce their own insecticide "the chance for insect adaptation is high".[34]

4.1.2.3 ***Sustainability*** is a concept open to several definitions, but all address the perceived need for agricultural systems to sustain the Earth's growing population by maintaining the viability of the biosphere.[35] Practices which use renewable or nonrenewable resources at rates which cannot be replaced by renewable resources, or which pollute the environment at rates which exceed the earth's capacity to degrade, recycle or absorb them, will prove unsustainable.[36]

Concerns over the impacts of GM technology focus both on the extent to which, by relying on intensive, chemically-based systems, they might over-exploit nonrenewable resources and pollute the environment, and on the risks associated with 'genetic pollution', whereby through horizontal gene transfer and genetic erosion the ecological balance might be seriously disturbed and sustainability thus challenged. Resistance genes (e.g. herbicides and antibiotics) are known to move readily between organisms so that "it is inevitable that some gene transfer will occur from certain crops" and "There are insufficient research data (on) possible effects (of HRCs) in the field environment".[37] Jeremy Sweet of the National Institute of Agricultural Botany, Cambridge puts the point more starkly: "Once we start growing transgenic oilseed rape on a big scale in the UK it will be everywhere".[38]

Moreover, with GM crops reliance on chemical inputs is likely to increase. According to Harvey: "Market domination by a handful of yield enhanced varieties will further standardise the landscape and concentrate production in the hands of large farmers all of whom will rely on the chemical companies for their seed."[39] In the same vein, Winfield observes that "applications of biotechnology that have emerged in the agricultural field do little to address the fundamental questions of environmental sustainability which have been raised regarding conventional agricultural practices. Rather, they seem designed to reinforce and further entrench such practices."[40]

Finally, sustainability may be challenged if the widespread use of GM crops encourages monoculture, which may make HRCs vulnerable to pest and disease epidemics.[41]



28 See note 22
29 Losey J E et al (1999) Nature 399, 214
30 Hilbeck A et al. (1998) Environmental Entomology 27, 1255-1263
31 Birch A N E et al (1999) Molecular Breeding 5, 75-83
32 See note 22, p.10
33 Dove A (1999) Nature Biotechnology 17 531-532
34 World Bank report: Bioengineering of Crops (1997): cited in note 81
35 Mepham B (1996) Agricultural Ethics in 'Encyclopedia of Applied Ethics.' ed Chadwick R San Diego: Academic Press. pp. 95-110.
36 Meadows DH, Meadows D L and Randers J (1992) Beyond the Limits: global collapse or a sustainable future. London: Earthscan
37 See note 22
38 Cited by Brookes M (1998) New Scientist No. 2158, p.40
39 Harvey G (1997) The Killing of the Countryside. London: Cape, p.129
40 Winfield (1997) Agricultural biotechnology and sustainable development. In 'Resource Management in Challenged Environments' eds. R W F Hardy, J B Segelken and M Voiionmaa Ithaca: National Agricultural Biotechnology Council, pp. 41-48
41 Gates P J (1995) Bioethical issues in crop production: herbicide resistance. In 'Issues in Agricultural Bioethics' eds. Mepham T B, Tucker G A and Wiseman J. Nottingham: University Press, pp. 151-162

4.2 PRODUCERS IN DEVELOPED COUNTRIES

4.2.1 Background

Although it is a gross simplification, there is merit in considering impacts of GM crops on farmers in developed countries separately from those in less developed counties, where the distinction between producer and consumer is often not clear cut. Major concerns for farmers are the costs and benefits of GM crops; their right to continue to produce food according to acceptable, alternative practices if they choose to, rather than be compelled to employ methods of which they disapprove; and impacts on farmers whose livelihood might be threatened by major shifts in world markets due to the introduction of GM foods.

4.2.2 Ethical Analysis

4.2.2.1 Impacts on conventional farmers

In the Ethical Matrix these are identified as respect for ***producer income and working conditions, freedom to adopt or not adopt GM technology*** and ***fairness in trade and law***, which are all closely interrelated by economic factors. While it is true that early adopters of the technology may benefit financially, at least in the short term, and that there could be reduced need for spraying the crop with pesticides and herbicides, farmers may subsequently encounter several problems. For example, as noted in 4.1.2.1, HRCs may be transformed into weeds, while HRC 'volunteers' may act as reservoirs of pests and diseases, undermining the principles of crop rotation.[42]

Where, as with one form of GM maize, the crop contains the gene for Bt toxin to kill the European corn borer, there may be an increase in the evolution of resistant strains of corn borer (4.1.2.2), and the rate at which this occurs will probably depend on the extent to which GM Bt crops are planted. This is now widely acknowledged, and a number of strategies have been considered for dealing with the problem. These include the use of 'refuges' where non-Bt plants are grown, to maintain a pool of sensitive insects that will prevent a Bt resistance gene spreading through the entire insect population. But this requires that farmers deliberately plant a part of their land with crops they know will either be lost, or will require insecticide treatment - an unlikely scenario. No mechanism for the enforcement of refuge planting exists, and anecdotal evidence suggests that in the USA it is rarely carried out.[43]

Another strategy is to vastly increase the level at which Bt toxin is produced in the plants, to levels where resistance may not evolve. Whether this approach will work cannot be judged in advance, but it would cause even greater problems for beneficial insects. The only other alternative would be to keep a string of new toxin genes in reserve, to be introduced when resistance evolves - in other words, to become involved in an arms race with the pest. This is not ultimately a winning strategy, locking farmers on to the so called, 'technological tread-mill.'

An alternative to reliance on pesticides, Integrated Pest Management (IPM), has been under development since the 1950s. This is a holistic approach to pest control which integrates various control methods in the light of a comprehensive assessment of the particular circumstances for each farm. Conway notes that: "As practised today it combines modern technology, the application of synthetic, yet selective, pesticides and the engineering of pest resistance, with natural methods of control, including agronomic practices and the use of natural predators and parasites".[44] The results can be highly effective, e.g. Conway , with reference to rice pests in India, cites the reduction in sprayings from four to less than one per season, with yields increasing 25%.

4.2.2.2 Impacts on organic farmers

One consequence of recent concerns over food safety and integrity is the greatly increased demand for organic products. Yet organic farming currently represents only a very small proportion of the total food output. Despite being the preferred option for many farmers, the extended conversion period (minimum two years, but generally longer), during which yields fall but are not entitled to attract the 'organic' premium, proves to be a significant deterrent. However, in the UK the amount of farmland in organic production has increased five-fold over the past year, and applications since April, 1999, when MAFF introduced a new Organic Farming Scheme to encourage conversion, will add a further 42,000 hectares to land already in organic production.[45] In the new scheme aid rates for better land have been almost doubled and spending increased from about £1million in 1998/9 to £6million this year, with a further increase to £8.5million next year. Whether the scheme will have a significant impact in promoting organic farming remains to be seen, but whatever the intentions it is almost certain that widespread use of GM crops would impede any progress made.

Thus, according to the recent Royal Society report: "Transfer of genes from GM to non-GM crops may also have unwanted effects if the latter are grown organically. ... Crops able to outbreed, such as maize .. will be affected to the greatest extent".[46] This poses a threat to organic farmers whose livelihood (cf. ***income***) depends on their being able to assure customers that their products are

42 See note 22, p.9
43 Pollan M (1998) Playing God in the Garden. New York Times Magazine 25.10.98
44 Conway G (1997) The Doubly Green Revolution: food for all in the 21st century. London: Penguin, p.215
45 MAFF (1999) Organic growth: Ministry scheme uptake News Release (2.8.99)
46 See note 22, p.7

free of GM material: the codes of practice of bodies which certify organic standards (e.g. the United Kingdom Register of Organic Food Standards - UKROFS), expressly prohibit use of GM crops.

Recently, scientific evidence has been produced underlining this threat: a report from the John Innes Centre states: "Genetic contamination of various kinds is inevitable in field grown crops".[47] The authors concluded that there is: "a need for acceptable levels of contamination of organic crops to be decided, and measures identified to achieve them ... complete isolation cannot be guaranteed". So at a time when public demand for organic food is at an all-time high in the UK and increasing rapidly, future progress looks destined to be undermined if GM crops become the norm in agriculture.

Proponents of GM crops suggest that such contamination is not a serious problem, citing the fact that organic standards accept a degree of chemical contamination (e.g. from pesticides). On the other hand, the strong public reaction to GM crops expressed in the UK, and other countries, suggests that such a comparison is not widely accepted.

However, this is not the only potential problem. The Bt toxin, the gene for which is expressed in several GM crops, is the *only* form of pesticide permissible in organic farming systems. Bt sprays are used quite sparingly at present (e.g. Pollan cites an organic farmer who only had to use it once in ten years),[48] making the evolution and spread of resistance far less likely than if it were persistently present in large numbers of crops. Thus, the likely development of Bt resistance through use in GM organisms is another threat to organic farming.

Challenges to organic farming from GM foods are thus not only that they might reduce ***consumer choice*** by monopolising the supermarket shelves but also that because of the uncontrolled spread of GM genes (which has been termed 'genetic pollution') the aspirations of those who wish to compete fairly in the market place might be frustrated, undermining respect for both ***fairness*** and ***producer freedom not to adopt*** GM technology.

The point is acknowledged by Nuffield, which *"recommends that the comprehensive and ongoing research into the environmental impact of GM crops should continue to be carried forward, with the specific objectives of obtaining sufficient information from such trials to control the effects from possible interaction of the GM crops both with native plant species and other agricultural crops, including organic crops" (N 7.44)* and, further that *"the Government should first undertake a broad environmental audit of the general implications of widespread use of GM crops and their impact on farming practices and the rural environment" (N 7.49).* However, the operative word is 'control': there is no suggestion that commercialisation of a GM crop should be conditional on satisfactory results from monitoring or the results of the audit. Such recommendations sit uneasily with the statement, *inter alia: "The moral imperative for making GM crops readily and economically available to developing countries who want them is compelling" (N Executive Summary p.xv).* It is important that criteria of assessment be established before trials are begun: this is an elementary requirement of scientific method.[49]

In discussing GM crops, the tacit assumption generally made is that the only valid comparison is between conventional intensive farming, as currently practised by the majority of farmers, and similar farming but using GM crops. Organic methods are given short shrift, as being incapable of producing the necessary yields from the land under cultivation. Although the benefits of organic types of farming in relation to species biodiversity and soil quality are widely acknowledged, these are ignored because of the assumed lower yields. But several long term studies indicate that this is not necessarily the case. For example, when maize yields were compared between a conventional, high intensity system, and two manure-based systems which used neither synthetic fertilisers nor pesticides, yields over a ten year period differed by less than 1% between the three systems. However, in the manure-based systems the soil fertility increased, whereas it decreased in the intensive system. Long term research in the UK shows that the average yield of wheat from manured plots is actually higher than on plots receiving complete nitrogen, phosphorus and potassium fertiliser, and that soil fertility increases on the manured plots much more than on the fertilised plots.[50]

4.3 CONSUMERS IN DEVELOPED COUNTRIES

The identified concerns here (cf. the Ethical Matrix) are ***safety and acceptability of GM food, choice*** and ***affordability***. We can say little about the latter because data are sparse on this point. When GM tomato paste was marketed in UK supermarkets it was sold at a lower price than the conventional variety. Whether this was because it was promoted as a 'loss-leader' is uncertain; but there appears to be little evidence from elsewhere (e.g. the USA) that GM techniques have led to cheaper food in the shops.

4.3.1 Ethical analysis

For most people, the ***safety*** of consuming GM foods seems to be the principal concern over their use, as illustrated by the panic surrounding the news of the alleged adverse effects of feeding GM potatoes to rats in February 1999. But, given that it is clearly in nobody's interests for food to threaten consumer health (the BSE crisis not only claimed several lives but also devastated the

47 Moyes C L and Dale P J (1999) Organic farming and gene transfer from genetically modified crops. Norwich: John Innes Centre, p.28
48 See note 43
49 Popper K R (1979) Objective Knowledge. Revised edition. Oxford: Oxford University Press
50 Tilman D (1998) Nature 396 211-212

livestock industry), we might now imagine that every effort would be made to ensure that consumers are not exposed to even remote risks from novel foods.

A comprehensive definition of ***wellbeing*** entails consideration of a wider range of issues: not only the safety of the foods and any added pleasure, or anxiety, that might be attributable to consuming them, but also questions of economics, the welfare of animals used in testing novel foods and impacts on the environment (i.e. ***acceptability***). However, within the compass of this discussion, a much narrower focus will be adopted - although many of the other issues are considered, if only summarily, elsewhere in the report. Thus, we concentrate here on physical (health and safety) effects of the introduction of GM foods on consumers.

As noted, most current GM foods are designed for agronomic advantages and confer no significant health benefits on consumers. Some such GM material is included in animal feeds and may thus have implications for the safety of humans consuming animal products such as milk and meat. In utilitarian terms, ethical issues relate to whether the use of the GM foods, or of such material in animal feed, on balance, benefits consumer wellbeing or presents risks to consumer health.

4.3.1.1 Safety of GM foods

With all forms of technology it is possible to identify hazards, i.e. theoretical risks. In some cases, where a statistical probability could be assigned to the likelihood of adverse effects resulting from a hazard, it is appropriate to refer to 'risks' rather than hazards. For simplicity, the more-widely used term 'risk' will be used consistently, although in few cases have the risks been subject to statistical analysis. While some categories of risk are common to many forms of GM crop, others relate to the specific genes incorporated into a crop's genome. A few examples will illustrate the types of risk identified.

4.3.1.1.1 *Antibiotic marker genes*

Marker genes, which are used in the process of developing a GM crop but confer no agronomic advantage, generally take the form of antibiotic resistance genes. However, the presence of such genes means that there is a small risk that antibiotic resistance will be transferred to humans, and thus compromise effective treatment of patients suffering from infectious diseases. According to the ACNFP: "the risk of transfer is small but finite. Functional gene transfer from bacterial to mammalian cells is certainly possible".[51] Resistance to antibiotics is a growing problem as a result of their extensive use in medicine and in agriculture, where routine addition to animal feed increases the growth rates of pigs and poultry.[52] Sir Robert May, the UK Government's Chief Scientific Adviser states: "Often (and arguably foolishly in my view) these marker genes are antibiotic resistant, so there could be a risk that humans could acquire these antibiotic resistant genes from their food, thus accelerating the already existing, and very troublesome, world problem of increasing resistance to today's antibiotics".[53] Indeed, concern over the such problems recently led the EC to ban the use of several antibiotics as 'growth promoters' in animal agriculture. It follows that any unnecessary use of antibiotics is a risk to human welfare.

In recent years, new ways of 'marking' transgenic crops have been devised or, alternatively, the antibiotic genes may be removed: both procedures have significant cost implications. The recent Royal Society report claimed: "it is no longer acceptable to have antibiotic resistance genes present in a new GM crop" [54], an opinion strongly endorsed in the BMA report.[55] Despite this, the majority of the GM crops in current use contain such genes.

4.3.1.1.2 *Allergenicity*

Allergic reactions are widely recognised as potential adverse effects of GM foods. Genes code for proteins; and proteins can be allergenic. Regulatory authorities are aware of this hazard and take measures to screen for allergenicity. For example, since 1992 in the USA the FDA's policy requires premarketing safety testing and labelling of foods containing genes transferred from the 8-10 most commonly allergenic foods.

That this precautionary measure was well advised is illustrated by the more recent demonstration that food allergens were transferred from Brazil nuts to soyabeans by transgenic manipulation.[56] As a result, the company concerned, Pioneer Hi-Bred, decided not to market its GM soya - but under the prevailing regulations it could have simply labelled the soya as containing Brazil nut genes and left the responsibility to the consumer. It has been claimed that because FDA requirements do not apply to foods that are rarely allergenic or to donor organisms of unknown allergenicity, the policy favours industry over consumer protection.[57] The BMA believes: "more research on issues around allergenicity and possible toxity of GM foodstuffs needs to be undertaken".[58]

4.3.1.1.3 *Toxic products*

It is theoretically possible that transgenes might code for toxic products. It would be no more difficult to produce a plant

51 See note 7, p.65
52 Food Ethics Council (1999) Drug use in farm animals: a Food Ethics Council report
53 May R (1999) 'Genetically modified foods: facts, worries, policies and public confidence.' London
54 See note 22, p.8
55 See note 19, p.10
56 Nordlee J A et al (1996) New England J Medicine 334, 688-692
57 Nestlé M (1996) New England J Medicine 334, 726-7
58 See note 19, p.9

containing a gene for a substance toxic to humans than it is to produce GM plants poisonous to insects. (Indeed, some of the most deadly toxins known are plant products -which opens up the possible dangers from biological warfare that have received scant consideration to date). But clearly no one in their right mind would deliberately produce toxins in food.

The concern is, rather, that a novel gene product might accidentally prove to be toxic, or cause allergies, perhaps only to a small sector of the population, if it becomes altered when produced in the plant. This also applies to traditional breeding - and there have been cases of such plants having to be withdrawn from the market because of unexpectedly high levels of toxins.

Although there appear to be no theoretical reasons why GM should be any more likely to cause this problem than traditional breeding, there has been very little published research addressing even the possibility of such unexpected consequences. The low priority assigned to testing is suggested by the report that in October, 1995 "there was little regard for the human nutritional and environmental consequences of GM foods" which led to a £1.6 million grant to Professor Pusztai at the Rowett Research Institute "to redress the balance".[59]

However, even if the novel genes themselves do not directly produce any toxic substances, there are further reasons for vigilance. This is because:

- small changes in the genetic make-up of a plant can produce significant changes in some of its secondary metabolites, which can be biologically active in a number of ways that might adversely affect the properties of the food.[60]

- novel transgenes may carry other genes with them and may also cause rearrangements in some of the plant's own genes when they are introduced.

Professor Pusztai's research, suggesting that consumption of raw GM potatoes containing a gene for lectin (an insecticidal protein) caused adverse effects on rats, was the source of the recent food scare over GM foods in general. But the research has not been published in an academic journal and a group of scientists set up by the Royal Society fundamentally disagreed with his conclusions.[61*]

However, in such circumstances, where the evidence is complex and technical, a non-expert (which includes the vast majority, including most biologists) is apt to adopt a precautionary stance. Nuffield states " .. *the case for damage to rats in long-term feeding trials is, on published evidence to date, at the most non-proven" (N 2.58).* In contrast, a reasonable person, recalling the reassuring official statements which preceded the revelation that BSE was transmissible to humans, might be inclined to assess the safety of GM foods as non-proven.

4.3.1.1.4 *Herbicide resistance genes*

In theory, HRCs allow the farmer to spray the crop freely with herbicide, killing all the competing weeds, but leaving the crop itself unscathed. The biotechnology companies producing HRCs also manufacture the herbicide to which resistance has been conferred - so that farmers buy the complete 'package' (seeds and weedkiller) from the same company. Various herbicides are in use, and while manufacturers claim that HRCs will enable an overall reduction in herbicide use, it is a clear commercial objective of each company that its own herbicide will be used more extensively. Hence, commercial competition might result in an overall increase in herbicide use.

Herbicides can be quite toxic substances for animal life as well as for weeds. Thus, glufosinate, to which one form of GM oil seed rape is resistant, is neurotoxic to a wide range of mammalian species, with dogs being particularly susceptible.[62] High level exposure in humans can lead to convulsions and memory loss. Because it is metabolised in the crop, human safety questions are raised by the possible adverse effects of its metabolites in the resulting food products.

4.3.1.1.5 *Safety assessment*

The uncertainty as to precisely how genes and their products interact within any organism (4.3.1.1.3) means that unforeseen consequences might arise. "Whenever you change the genetic composition of an organism the probability is that you will get metabolites you did not expect. Concerns like this justify asking for safety protocols equivalent to those for pharmaceuticals".[63] Indeed, the more common the production of GM crops becomes, the more likely it is that unpredicted effects will be observed - and at least some could have adverse effects. A joint ACNFP/COMA working party report noted that "change is happening at an accelerated rate and there may be interactions between nutrients".[64]

However, there are serious difficulties in attempting to treat food like drugs in this respect. It is almost impossible to feed laboratory animals enough GM food to see whether it has adverse effects compared with normal food, partly because such quantities may be unpalatable and partly because of physical limitations to food intake. And even if it were possible to get the test animals to consume large amounts of GM food, the effects of

59 Flynn L et al in The Guardian 12.2.99, p.6
60 Firn R D and Jones C G (1999) Nature 400 13-14.
61 http://royalsoc.ac.uk.st-pol54.htm. ***Note added at proof stage.** But according to the Guardian (5.10.99, p.2): "The Lancet, the international medical research journal, will next Friday contain a paper showing changes in the guts of rats fed GM potatoes, raising questions as to why these may have occured." The paper, by Professor Pusztai, "was reviewed three times by other scientists before being accepted for publication by the journal, which said that its papers went 'through the mill' first."
62 Cox C (1996) J Pesticide Reform 16, 15-19
63 Goodwin B (1997) in 'The Future of DNA' ed. J Wirz and E T Lammerts van Buren. Dordrecht: Kluwer, p.266
64 See note 7, p.60

changing the diet so markedly could well invalidate any results obtained. For example, rats fed freeze dried powder of GM tomatoes consumed the equivalent of 13 fresh tomatoes per day. "Any more, and they would have been poisoned by the basic nutrients such as potassium, in the tomato powder".[65] The head of scientific affairs at a major biotechnology company is reported to have said that, to circumvent difficulties of this type: ".. we put the novel genes into bacteria, produce the gene product and test it by conventional methods". However, as pointed out by MacKenzie, "the protein made by the bacteria may not be the same as that made by the plant, especially in its potential to cause allergy."[66]

Nuffield acknowledges the impossibility of pharmaceutical-type toxicity testing of GM foods *(N 2.55)* and appears to support the view that if a product is 'substantially equivalent' (see 2.7) to a non-GM product no new forms of assessment are required *(N 2.56)*. However, according to the BMA : "..that certain novel genes inserted into food may cause problems to humans is a real possibility, and 'substantial equivalence' is a rule which can be used to evade this biological fact".[67]

It is probably not too inaccurate to claim that people who endorse the production of GM foods do so largely from a utilitarian perspective which considers that the overall benefits to consumers far outweigh any risks. In any event, it needs to be recognised that no system of food production can be risk-free, and technological advances have certainly been responsible for some major advances in food safety.

We have seen, however, that there are certain problems with the proponents' claims. Thus, there are the problems of knowing what to look for in making safety assessments; of deciding what level of known risk is to be regarded as 'safe'; of assessing that risk by scientific procedures; and of comparing any such calculated risk to the prospective 'benefits', which might be deemed to outweigh them.

4.3.1.2 Consumer choice

The autonomy interests at issue with relation to consumers have been those of ***choice***, sometimes expressed in terms of a right to alternatives, including organic foods; and access to relevant information.

4.3.1.2.1 *Choice*

Says John Gray "Consumers do not want to buy genetically modified food. Supermarkets do not want to sell it. Farmers do not want to produce it".[68] The argument from choice tends to be cashed out in terms of alternatives to novel foods - including organic foods. Although this might appear clear and straightforward, on closer inspection it is complex and potentially problematic. Focus on consumer choice implies that 'the consumer' wants to choose, personally, whether to consume GM food or not. However, individuals may be concerned about GM food not for personal reasons but because of their wider concerns e.g. the long term consequences for the environment, the effect on developing countries, and the underlying assumption that nature is there to be used solely for the benefit of human beings.

Nuffield acknowledges that "*for some consumers in the UK and the EU, the avoidance of GM foods is itself the good they seek*" *(N 1.15)* but state that for most the choice whether to consume or not consume GM food is not a matter of ethics *(N 1.16.)*. They suggest that there is a sense in which individuals have a right to reject goods that are offered without giving any reason (N 1.17) but also imply that if it is not based on avoidance of harm, justification is required, i.e. "*A demand for consumer choice not based on harm needs to be justified in the context of regulation to politicians, regulators and food producers" (N 1.15).*

This is important because it is not always clear whether 'choice' itself is, and should be, valued in public policy decision-making or whether (although it may be difficult to present an argument against choice as such) what is really valued is choice that is construed as rational. If the latter, the question arises as to whose standards of rationality are to prevail. Underlying motivations are recognised as complex,[69] as is the relation between values and what consumers actually buy. Sociological research on consumption shows that we cannot unquestioningly adopt a model of 'rational self-interested consumers', who are concerned with wellbeing understood simply in terms of health and safety. Consumption may be intricately associated with perceptions of self-identity. By our habits of consumption we make statements about who we are, or perceive ourselves to be. Then there is the issue of the content of choice, or range of choice; and the choice of the kind of world in which people want to live.

Nuffield recognises that a choice may not be 'real'. Consumer choice needs to be examined with reference to the availability of alternatives, the power of certain groups to define what foods are healthy or appropriate e.g., culturally and morally, and the constraints of an individual's economic and social situation.

65 MacKenzie D (1999) New Scientist No. 2182, pp.18-19
66 See note 65
67 See note 19, p.8
68 Gray, J (1999) 'Misguided man' in the 'Guardian' 31.7.99
69 European Federation of Biotechnology (1999) Ethical Aspects of Agricultural Biotechnology The Hague: Cambridge Biomedical Consultants, p.18

4.3.1.2.2 ***Information.***

We have seen that there are essentially two issues connected with consumer choice:

- the right to information and
- the right to alternatives.

As regards the first, what is meant when we say that people want information? A line of argument from the perspective of autonomy, interpreted in terms of self-determination, might enable consumers to make informed decisions about nutrition; and avoid foods which they perceive as bad for them or inappropriate to their lifestyle and beliefs. This might also be supported by an argument from a 'welfare' perspective to enable consumers to avoid ingesting substances that are, or are perceived as, harmful.

When we say that consumers have a right to know what they are eating and drinking, however, the distinction between information and knowledge has to be addressed. Some claims about food may be based on preliminary research. Neither consumers nor scientific experts can be 'fully aware of the facts', since not all research is published or in the public domain. Published research based on quantitative measures of risk can provide 'facts' but concerns about longer-term effects are speculative. Dietary guidelines are repeatedly revised by experts, e.g. quite recently with respect to red wine consumption.

Moreover, consumers may be bombarded with conflicting claims. The volume of information, itself, may be so great that it proves a bar to the enhancement of autonomy, as has been argued in the case of medical genetics,[70] and to the fulfilment of a right to know or at least a right to understand. Understanding is not necessarily enhanced by provision of information. This is particularly significant with regard to the issue of labelling. To focus attention on what should and should not be included on a label, while important, does not settle the issue, because there are deeper questions about how we should interpret concepts such as information, knowledge and understanding, in addition to questions about the best practical means of achieving these.

The 'deficit model' of public understanding relies on a view which prioritises a scientific model of knowledge (and the provision of information to alleviate the deficit) while playing down 'lay' interpretations of developments in genetics.[71] Surveys of public opinion indicate a lack of trust in the assurances of government agencies and scientists.[72] In contrast, the large supermarket chains have been shown to enjoy a high degree of trust among consumers. Nuffield recommends research to establish what information consumers want and in what form it would best be provided. *(N 5.52)*. While it is difficult to disagree with this recommendation, it does not go far enough in addressing the difficult issues raised by the choice argument.

With regard to the second point, when choice is concerned with alternatives to GM foods, Nuffield recognises that if people are to have a choice to avoid them, this imposes an obligation on others to see that they are available. This highlights the point that within the Matrix, the choice argument has to be weighed in the light of considerations of justice - with regard both to different groups of consumers (the choice argument has been most prominent as applied to the western consumer) and to the impact on other interest groups.

4.4 PRODUCERS AND CONSUMERS IN LESS DEVELOPED COUNTRIES

4.4.1 The moral imperative of fairness

From the perspective of a developed country which has the power to significantly affect the food supplies of less developed countries, there can surely be no more pressing consideration than that of ***fairness***. There are, however, several different ways in which people understand the term. Does it, for example, suggest that goods should be distributed primarily according to need, or to ability, or to effort? The concept of fairness advanced here regards fairness a moral obligation to try to compensate for the vast inequalities of circumstance and opportunity which randomly affect humanity and which it is both a right for those less privileged to receive and a duty for the privileged to observe. This is a view of fairness that accords with the definition of justice proposed by the American philosopher John Rawls.[73] It is not envisaged, unrealistically, that all can have equal opportunities, wealth, talents etc but that in a just, liberal society, "the sum of transfers and benefits from essential public goods should be arranged so as to enhance the expectations of the least favoured."[74]

When we consider food in a global context we are immediately confronted with the most startling evidence of global injustice.[75] Hundreds of millions of people are born into, and live their (for many, very short) lives in, conditions of extreme poverty and hunger: the United Nations estimates that 1.3 billion survive on less than $1 per day.[76] Even within, so-called, developed countries, there are also vast disparities of wealth and hence diet-related illness. Thus, according to the definition of fairness adopted here, there is currently a situation of extreme unfairness with respect to food availability. The question facing us is whether the introduction of GM foods could, or perhaps more importantly, is likely to, ameliorate this situation or exacerbate it; and what

70 Danish Council of Ethics (1992) Ethics and the Mapping of the Human Genome
71 Kerr A et al (1998) Public Understanding of Science 7, 113-133
72 Grove-White R et al (1997) Uncertain World: University of Lancaster
73 Rawls J (1972) 'A Theory of Justice'. Oxford: Oxford University Press, p. 302.
74 See note 73, p. 304
75 Dower N (1996) Global hunger: moral dilemmas. In 'Food Ethics' ed. Mepham B. London: Routledge. pp. 1-17
76 UNDP (1998) Human Development Report. New York and Oxford: United Nations Development Programme/ Oxford University Press, p.10

implications such consequences would have for our ethical assessment of their use. In discussing fairness in this context we are implicitly encompassing considerations of respect for ***wellbeing*** and ***autonomy*** (as defined in the Ethical Matrix).

4.4.2 The impact of GM foods on global hunger

The great majority of the hungry people in the world live in less developed countries' (also referred to as 'developing countries' or 'the Third Word'), but their condition is not, as is often suggested, primarily due to lack of food in the marketplace. As Nobel Prize winner Amartya Sen has pointed out, the famines which afflicted so many in India in 1943 and in Africa, the Sahel and Bangladesh in 1974 were not due to market failures but to poor people's inability to buy food.[77] Thus, GM foods are only likely to reduce world hunger if they benefit less developed societies either by increasing the wages of the poorest (e.g. by creating rewarding employment) or by fundamentally improving the productivity of staple foods.

Up to now, the great majority of applications of genetic engineering in crops have involved production of HRCs for western markets, e.g. maize, soya and oil seed rape, which are all used in processed foods and in animal feed.[78] Such applications are suited to food systems which depend on processing and adding value to food products. "In general, the applications of agricultural biotechnology which have emerged to date have been closely integrated with conventional, capital-intensive agricultural practices employed in North America and Western Europe. Such trends do little to improve food security in the South".[79]

4.4.2.1 The Green Revolution

Despite this, Nuffield places great faith in the ability of GM crops to *"alleviate under-nutrition and malnutrition" (N 4.19)*. Indeed : *"The moral imperative for making GM crops readily and economically available to developing countries who want them is compelling"(N Executive Summary p. xv)*. Apparently, *"this is because GM crops are expected to produce more food, or more employment income for those who need it most urgently" (N 4.3)*. Nuffield's case appears to rest on the precedent of the Green Revolution, the introduction of high yielding varieties of wheat and rice, produced by conventional breeding, which occurred in the decades following 1960.

Others have been less enthusiastic about the results of the Green Revolution. According to Bennett, basing his comments on wide experience of less developed countries: "The Green Revolution did produce more food and enrich some farmers, but as a solution to global hunger it was an expensive failure. In most places it has widened the gap between rich and poor and has been the cause of social upheavals in peasant cultures. In fact, it has not only failed to improve the lot of the poor, but it has also caused widespread ecological problems."[80]

A recent Christian Aid report claimed that the Green Revolution:[81]

- focused on wheat and rice, missing out poor farmers who grew sorghum, millet and beans
- locked farmers into dependence on seed companies, raising farm costs and benefiting larger farmers and agrochemical companies
- concentrated ownership of land into fewer hands as rich farmers drove out the poorer.

Indeed, despite Nuffield's apparent support for the Green Revolution *(e.g. N 4.20)*, Professor Lipton, a member of its working party, wrote in 1989 of the "persistent mass poverty in parts of the 'green revolution' heartland" and remarked that innovations "helped the better off rather than the poor".[82] These strictures might equally apply to the potential innovation of GM crops in less developed countries. By disempowering the small farmer and placing even more power in the hands of corporate industry they fail to address the critical criterion for 'sustainable livelihood security' which was proposed by the Brundtland Commission in 1987, viz.

"National research priorities in the field of agriculture and rural production should explicitly emphasise the generation of new knowledge and the adaptation of existing knowledge directed specifically to the amelioration and sustainability of the agricultural production in the poor farm sector." [83]

4.4.3 What are the prospects that GM foods will be used to reduce hunger and aid development?

With the end of the Cold War, foreign aid to less developed countries ("which sought to win the hearts and minds of the developing and decolonized world") is no longer seen as essential in geopolitical terms, with the result that the fiscal basis of international agricultural research has begun to erode.[84] In less developed countries public funding per scientist has declined substantially since 1980, and the pressure to support sustainable agriculture has been seen as "largely coterminous with limiting the scope of biotechnology". Instead, research on GM crops, and indeed all forms of biotechnology, has now become concentrated in private hands. "Five major agro-chemical/seed companies control most of the agricultural applications world-wide,"[85] and it is clear that their commercial objectives are best served by

77 Sen A (1981) Poverty and Famines: an essay on entitlement and deprivation. Oxford: Clarendon Press
78 Food and Drink Federation (1997). Food for our Future. London
79 See note 40
80 Bennett J (1987) The Hunger Machine. Cambridge: Polity Press, p.23
81 Christian Aid (1999) Selling suicide: farming, false promises and genetic engineering in developing countries. London, p.5
82 Lipton M and Longhurst R (1989) New seeds and poor people. London: Unwin and Hyman, cited in note 81
83 World Commission on Environment and Development (1987) Food 2000. London: Zed Books. p.112
84 Buttel F H (1995) The global impacts of agricultural biotechnology: a post-Green Revolution perspective. In Issues in Agricultural Bioethics. eds. Mepham T B, Tucker G A and Wiseman J. Nottingham: University Press. pp. 345-360
85 House of Lords (1998) Select Committee on European Communities: EC Regulation of genetic modification in agriculture (15.12.98), p.1

concentrating on products which satisfy the demands of Western consumers. But agriculture in developed countries is totally different from that in the developing world, not least because in comparison with less developed countries, the agricultural workforce is such a small percentage of the total population (just 2% in the UK).

Such factors apparently weigh heavily even for some who are sympathetic to the claim that biotechnology has the potential to meet human needs. Thus, the distinguished agricultural ecologist, Gordon Conway, President of the Rockefeller Foundation, considers that "more important than the potential [ecological] hazards ... is the question of who benefits from genetic engineering ... [which] is a highly competitive business and inevitably, the focus of biotechnology companies has been on developed country markets. ... If the work is privately funded, the products may be expensive and protected by highly restrictive patents". [86] Moreover, the House of Lords Select Committee noted the "... concern, shared by farmers, witnesses and ourselves, that the powers of a few agro-chemical/seed companies are already great, and will become greater, over the process of producing (developing and growing) genetically modified crops."[87]

In contrast, Nuffield seems to downplay this issue, making several references to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), which it recommends *(in N 8.42 and 8.45)* should play an important role in the commercialisation of GM crops in less developed countries. (It should be noted, however, that this organisation receives funding from several agricultural biotechnology companies, as well as from USAID and charitable sources).[88] But even Nuffield appears to betray a lack of faith in its own prescriptions when it states: "*With appropriate emphasis and incentives in GM crop research, **and with luck**, GM crops could raise calorie and economic yields per hectare ....*" *(N 4.43)* [our emphasis].

However, according to Eastmond and Robert, "R&D from developed countries will largely reach less developed countries through two channels viz. incidentally, as a by-product of research done for other purposes, and if it is directed through multinationals which have a stake in the region. In both cases patents will ensure that less developed pay dearly for the new technology".[89]

Even were GM crops to be appropriate for less developed countries, the paucity of research effort would almost inevitably undermine efforts to realise substantial benefits. Indeed, Nuffield's recommendation *(N 4.48)* that "*the UK Government should pre-commit a substantial amount of the UK aid announced in July 1998 to additional spending on the R&D of GM staples grown in developing countries*" seems unlikely to make any significant impact, because the concentration of R&D, in the context of patents and emerging IPR (intellectual property rights) regimes, militates against potential benefits going to small scale farmers (and poor countries in general).

The moral obligation for developed countries to greatly increase investment in R&D for less developed countries can hardly be questioned; but whether it should be primarily directed to GM crops is highly problematical (e.g. see 4.4.7).

4.4.3.1 Technical limitations to GM crops in relieving hunger

Apart from political constraints, there are also technical limitations to applying the GM approach to less developed countries, as discussed in 2.5. Plant transformation (the ability to get genes into plants and for them to become stably inherited) is not an exact science, and some plant varieties are notoriously hard to transform. At present, many poorer farmers plant a large number of different varieties of the same crop, as a sensible precaution against fluctuations in climate or pests. This is not a good strategy for maximising yield - as some varieties may be relatively low yielding - but it safeguards against total crop failure.

The development of GM crops is also an expensive process. Thus, there must be concern that focussing on GM crops as a central part of the strategy to ameliorate hunger would divert much needed funding from other less glamorous but more effective programmes. To consider just one example: it has been argued by some that rather than attempting to develop nitrogen fixation in monocots, more attention should be paid to improving the so far unexploited characteristics of legumes which are not yet in commercial cultivation but which are already well adapted to the more extreme conditions that limit agriculture. The traditional approach of letting land lie fallow for long periods, which characterises sub-Saharan agriculture, is under pressure because of dwindling land resources, but the use of chemical fertilisers is too expensive an alternative and in any case does not deal with the loss of organic matter from the soil. However, many tropical legumes, which farmers currently often regard as weeds, have significant unexploited potential for use as green manures in these areas. But the resources available for plant collection and field study in this area have dwindled in recent years as investment in the high technology end of plant breeding has increased.[90]

4.4.3.2 The risks of encouraging monoculture

It could be argued that the most effective way to counter global food shortages and poverty is not to encourage people to grow

86 See note 44, p.159
87 See note 85
88 Wambugu F (1999) Nature 400, 15
89 Eastmond A and Robert M L (1992) Advanced plant biotechnology in Mexico: a hope for the neglected? In 'Biotechnology: a hope or a threat?' ed. Ahmed I. Basingstoke: MacMillan. pp. 65-78
90 Dreyfus B (1998) 'How to exploit the diversity of tropical symbiosis for sustainable agriculture: fallow legumes and rhizobia associated to wild rice'. In 'Biological Nitrogen Fixation for the 21st Century'. Kluwer Academic Publishers, pp. 617-618

their own food, but to put their effort into farming for cash crops - something which is, of course, already practised extensively. This approach would favour widespread adoption of GM, as it would require just a few high yielding crops with defined management regimes. But many problems may arise with this approach. The management regimes often require substantial inputs of expensive fertilisers or pesticides to give marketable yields, favouring the expansion of larger, less labour intensive farms. Cash crops are very susceptible to fluctuations in futures and commodities markets - factors which are completely beyond farmers' control - and so do not provide a guaranteed income. They are also susceptible to technical developments that allow the production of some substances by non-agricultural means such as tissue culture, which can rapidly change the market value of the crop.

The widespread cultivation of cash crops is also likely to lead to a rapid loss of local and indigenous knowledge about food crops, which may have been built up over many generations and transmitted only orally: once lost, this knowledge might be irrecoverable. Finally, the use of cash crops for income requires many more middlemen between the farmer and final buyer, which means the proportion of the income from the crop returned to the farmer may be substantially reduced.

GM approaches, however effective they might seem to be, are unproven and risky technologies for both developed and less developed countries. This caveat does not, however, imply that use of GM for cash crops should be ruled out categorically. It is certainly possible to envisage appropriate uses: the crucial question is whether they can be embedded in a system which is sustainable overall.

4.4.3.3 Sustainable development

It is significant that the recent Annual Report of the UK Department for International Development's (DFID) makes many references to sustainable agriculture in its 172 pages, but none to GM crops.[91] They are clearly not assigned a high priority - in terms of time, effort and resources - by a Department that has defined its primary objective as the eradication of abject poverty in the world's poorest countries.[92] To further the objective of poverty eradication, the Department's increased resources appear to be more effectively used in building the capacity of less developed country governments to deliver basic education, primary and reproductive healthcare, and other key social services; and on support for rural livelihoods and the natural resource base on which they depend.

The circumstances of less developed countries might seem to demand a totally different approach to those applied in the West, albeit now with increasing reservations. Thus, Weiler, noting the large reservoir of labour in developing countries and the need for agricultural development, identifies the desirability of the following:

- limitation of the mass migration to large cities (the phenomenon of the megapolis), which will produce almost unmanageable social problems
- stimulation of local agriculture so that the population achieves self-supporting food production
- continuous investment to improve local agriculture, e.g. irrigation, soil erosion control, mechanisation etc.[93]

It is highly questionable whether GM crop technology, certainly on the basis of evidence to date, could facilitate any of these objectives: more likely it would frustrate them.

Tansey, noting that the trend towards stronger IPR regimes, coupled with the switch to private funding of R&D, is changing the nature of research, suggests that there is a need for a reorientation of public R&D. He claims that one way to contribute to the elimination of poverty, the enhancement of food security and the conservation of biodiversity is to "support applied research and rights regimes that provide solutions to the problems faced by small farmers. In principle, the products of such research could create a more competitive marketplace giving alternative solutions to farmers to the copy-protected, biotechnology-based products being developed rapidly by the private sector."[94]

4.4.4 *Terminator technology*

Even those GM crops which might be grown in less developed countries seem likely to raise critical problems. Thus, a threat is posed by the, so-called, 'terminator technology', which by incorporating two or three novel genes into a plant, causes the seed to die in the early stages of germination.[95] This denies farmers the right to reuse seeds saved from previous harvests. The company which developed the technology argued that it will benefit world agriculture by ensuring that all seeds planted will be highly productive, but it could have socially disastrous effects since, currently, 1.4 billion people are dependent on crops grown from seed saved by small farmers in the developing world. Up to 70% of seeds used by such farmers is saved on-farm.[96]

DFID recently made an undertaking, with respect to its own funded activities, "not to develop, test or use breeding material which incorporates genetic systems designed to prevent seed germination (so-called terminator gene technology) until and

91 Department for International Development (1999) (DFID) Report: the Government's Expenditure Plans 1999-200 to 2001-2002
92 White paper on International Development (1997): Eliminating World Poverty: a challenge for the 21st century
93 Weiler R (1999) Biotechnology shaping a new agriculture: societal aspects. In 'Proceedings of the first European Congress on Agricultural and Food Ethics': Wageningen' (4-6.3.99), pp.5-10
94 Tansey G (1999) Trade, Intellectual Property, Food and Biodiversity: London: Quaker Peace and Service. p.23
95 Steinbrecher R A and Mooney P R (1998) Ecologist 28, 276-286.
96 Cromwell E (1997) in New Seeds and Old Laws. ed. Tripp R. London: Intermediate Technology Publications. p.218

unless such technology has been shown and agreed to be appropriate and beneficial for the developing country or countries concerned".[97]

Nuffield, however, takes a different view, stating that *"The monopoly control, or non release to poor farmers ... could be similarly defended. It is a right that seed developers should be able to obtain normal, market profit on their full investment, including R&D, and also some reward for risk taking and for special scientific skill or business judgement" (N 4.75).* Nuffield is reassured in this opinion by its belief that the Monsanto company, which recently acquired this technology, *"contains scientists of high ethical as well as scientific quality" (N 4.76)*†.

However, it might be argued that Nuffield overlooks, in this support for the 'reward for risk-taking' argument, the current move towards consideration of an ethic of benefit-sharing in the pharmaceutical industry and elsewhere, in the light of concerns about developments such as 'biopiracy', considered below.

4.4.5 Biopiracy

It is claimed that less developed countries are unfairly treated by the process which has been labelled 'biopiracy'. Vandana Shiva gives a poignant example in describing the Neem tree, which is widely grown in India. The tree and its leaves possess a remarkable range of properties (such as its antimalarial, contraceptive and anti-infective properties) which have been utilised by generations of Indians. Now, however "you have about ten companies which have patents on its biopesticide properties. So every aspect of Neem that has been known in India is being treated as an innovation of a Western corporation".[98] A UN report published in 1994 concluded that biopiracy was "cheating developing countries and their indigenous peoples of some $5.3 billion p.a.".[99]

4.4.6 Product substitution

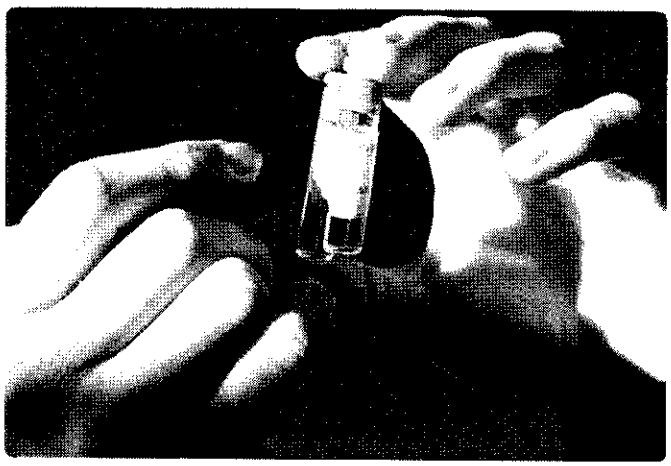
Severe effects on the economies of certain less developed countries may also be anticipated as a result of product substitution. For example, the livelihoods of an estimated 10 million sugar farmers in less developed countries are threatened by the marketing of GM sugars and sweeteners, which are being grown and processed in developed countries: it is estimated that GM fructose production has already captured 10% of the global market. GM canola (spring rape), currently tested in the UK, may be used to replace coconut and palm oils, thus threatening the employment of the 21 million people in the Philippines who are involved in coconut oil production.[100]

4.4.7 Conclusions

Along with issues of wellbeing and autonomy, respect for justice (here expressed as 'fairness') is a fundamental right enshrined in documents such as the UN Declaration of Human Rights. Clearly, fairness, or the lack of it, can be practised in relation to virtually any human activity. For example, education and health are indisputably 'good' but they can be allocated unfairly. Is there something intrinsically unfair about novel foods and/or are they liable to be applied unfairly?

Commercial imperatives appear to dictate that expensive and innovative technologies such as those involved in producing GM novel foods fall into the hands of very few players: five multinational companies dominate world production of GM foods. It can hardly be doubted that such a concentration of power poses serious threats to the fragile economies of many less developed countries. And even if there were no intrinsic bias against poorer societies, the evidence from the way in which the biotechnology industry has so far developed provides few grounds for optimism.

Undoubtedly, an important consideration is the opinion of representatives of those nations at whom Nuffield's alleged benefits of GM food are primarily directed. In June, 1998, delegates of 24 African countries (excluding South Africa) to the United Nations' Food and Agriculture Organisation (FAO) issued a statement refuting the claim that less developed countries would benefit from GM technology. Instead, the delegates' statement claimed that promotion of GM crops will "destroy the diversity, the local knowledge and the sustainable agricultural systems that our farmers have developed for millennia and that it will thus undermine our capacity to feed ourselves".[101]



97 DFID (1999)Background Briefing Paper: Genetically modified organisms and developing countries.
98 Cited by Reiss M J and Straughan R (1996) Improving Nature?: the science and ethics of genetic engineering. Cambridge: Cambridge University Press, p. 154
99 See note 98, p.155
100 Nottingham S (1998). Eat Your Genes. London: Zed Books, p.165
101 See note 81, p.4. The statement was made during negotiations on the International Undertaking on Plant Genetic Resources.
† **Note added at proof stage:** According to the 'Guardian' (9.10.99, p.5), Robert Shapiro, head of Monsanto, has stated that "the company would no longer pursue research into the Terminator technology". This apparently followed a meeting at which Professor Conway, President of the Rockefeller Foundation, "argued that the possible adverse consequences for billions of developing farmers outweighed any social benefits in protecting Terminator technology".

4.5 AN ETHICAL EVALUATION OF GM FOOD CROPS

Our 'weighing' of the ethical impacts discussed above leads us to the following ethical evaluation of GM food crops:

❑ Despite the claimed environmental benefits of certain GM crops, in terms of reduced use of herbicides and pesticides, there is evidence of a potential for serious harm to wildlife through cross pollination, the development of herbicide and insect resistance and genetic erosion (with consequent risks of disease epidemics). Unlike most other forms of technology, unforeseen problems with biotechnology could be almost impossible to correct because GM organisms colonise the wider environment. (4.1.2)

❑ Conventional farmers who adopt GM crops early might benefit financially from increased yields and reduced use of chemicals (although the evidence is not clear) but the likely requirements for 'refuges' and the evolution of pest and herbicide resistance could cause significant problems after a few years of use. (4.2.2.1)

❑ Organic farmers are seriously threatened by GM crops, both because of almost inevitable cross pollination (infringing the compositional criteria for organic produce) and because of the evolution of resistance to Bt toxin, the natural, and only, insecticide which organic farmers are permitted to use. (4.2.2.2)

❑ Although there is currently no direct evidence of physical harm to consumers through consuming GM food, the novelty of GM foods implies that they need to be subjected to rigorous safety testing, e.g. for allergens. (4.3.1.1.2)

❑ Respect for consumer choice suggests that consumers who wish to avoid GM food should be given that opportunity - by appropriate labelling and ensuring supplies of non-GM food. (4.3.1.2)

❑ The principal need in less developed countries is for technologies which generate income for small farmers while promoting sustainability and discouraging dependency, but the case has not been made that use of GM crops would promote these objectives. On the contrary, it might frustrate them. (4.4.1)

❑ Producer and consumer autonomy is threatened by the increasing concentration of control of global food supplies into the hands of a very few, very powerful multinational biotechnology companies. (4.4.3)

❑ Because a systematic comparison of different agricultural practices (GM, conventional, organic etc.) has not been performed, the relative merits of the different systems have not been established. Hence, approval of GM crops, which could fundamentally alter the nature of global food production, might be considered premature.

5. FUNCTIONAL FOODS

5.1 Background

Functional foods may be discussed in relation to their claimed prospective benefits. For example, some are claimed to:

- *promote early development*, which may have important effects not only on short-term growth, body composition and physiological function but also on long-term prospects for health, disease and mortality. For example, folic acid supplementation from before conception to the first weeks of pregnancy markedly reduces the incidence of embryonic malformations. [102]

- *prevent disease*, e.g. cardiovascular disease (CVD) is believed to account for over 40% of deaths in the UK. The underlying cause is atherosclerosis (thickening and reduced elasticity in arterial walls), which is influenced by several genetic, metabolic (e.g. high blood cholesterol levels) and lifestyle factors (e.g. diet and smoking). A study of 7000 men in Scotland showed that lowering blood cholesterol concentration by 20% (using drug treatment) was associated with a 33% reduction in coronary heart disease, a form of CVD.[103] Since prophylactic drug therapy would be prohibitively expensive, attention has turned to the role of functional foods in reducing blood cholesterol levels.

The principal ethical concerns relating to functional foods are identified from the Ethical Matrix in terms of ***food safety, choice*** and ***affordability***. Will functional foods be free of hazard for all likely consumers; will consumers be able to exercise choice; and will the benefits of functional foods be fairly available to all who need them, irrespective or their income and/or level of awareness? To recognise that such conditions are rarely met in other aspects of life does not detract from their relevance in the current context.

5.2 ETHICAL ANALYSIS

5.2.1 Food safety

Assessment of novel functional foods encounters some of the same problems that were discussed in relation to GM foods (4.3.1.1.5): it is not possible to test foods by feeding large doses to experimental animals, and almost by definition functional foods

102 Koletzco B et al (1998) Br J Nutrition 80, supplement 1, S5-S45
103 Sessions V A et al (1998) In 'Functional foods: the consumer, the products and the evidence'. eds. Sadler M J and Saltmarsh M. London: Royal Society of Chemistry. pp.15-19

will not show substantial equivalence with 'normal' foods. Judicious testing on human volunteers might be the only reliable method. But, since certain functional foods, and especially nutraceuticals, are likely to be specifically designed for people with particular medical needs (e.g. to ameliorate disease or prevent it in particularly vulnerable individuals) testing that is more equivalent to that employed for pharmaceuticals might not be deemed inappropriate.

There are also recognised concerns over possible cumulative effects of small changes in the composition of an increasing number of foods.[104] For example, a slight change in the fatty acid content of any individual food might be unimportant; but the consequences of consuming several such food products could be quite significant.

5.2.2 Choice

The general issues associated with this principle have been discussed above (4.3.1.2) but with functional foods it assumes a particular significance. There is a need to ensure that consumers are not misled into believing that a particular food product has unequivocal benefits, especially if those benefits might be secured more effectively, and possibly at lower cost, by other means. For example, equally or more effective ways of avoiding a particular disease might lie in changes in diet, or in lifestyle more generally.

The potential for misunderstanding is very real because, according to a leader article in the British Medical Journal, "the dividing line between foods and drugs is becoming increasingly blurred.[105] The authors of the article noted that in the United States "a chewing gum with phosphatidyl serine" is claimed to "improve concentration", in Japan a soft drink fortified with ß carotene "supports a healthy lifestyle", while in the UK "a butter-like spread made with fish oil [is claimed] to benefit the heart"

5.2.3 Affordability

To the extent that functional foods blur the distinction between foods and medicines, it is not difficult to foresee that their increasing popularity could exacerbate the widening gulf between the health status of richer and poorer sectors of society. If functional foods, and consequently improved chances of health, were to become the preserve of the wealthy, those unable to afford such foods would be just as much the victims of unfair treatment as if they were unable to afford medical treatment.

5.3 Examples of functional foods

5.3.1 Cholesterol lowering foods

It has recently been claimed that a milk product fermented with a culture of *Enterococcus faecium* and *Streptococcus thermophilus* specifically reduces blood plasma concentrations of cholesterol in males.[106] Whether or not these claims are made in marketing, it seems likely that such a product could gain the reputation of conferring health advantage on the basis of scientific evidence. However, when the cholesterol-lowering properties were examined by a different group, no significant effect was observed.[107]

The results underline the need for standardised, independent, blind trials in order to assess their safety, quality and efficacy. Indeed, there might be a case for re-defining functional foods as medicines if there is any claim or implication that they confer specific health benefits.

5.3.2 Dietary supplementation

On the other hand, the marketing of certain functional foods which produce effects not easily otherwise replicated might be seen as beneficial to consumers with identified nutritional requirements. "Decades ago iodised salt vanquished iodine deficiency goitre. Today orange juice fortified with calcium helps strengthen bones, folate enriched flour helps prevent neural tube defects, and grain products fortified with oat bran or psyllium may help reduce the risk of heart disease".[108] If it is fair to warn people of the dangers of eating too much red meat, is it not also fair to advocate supplemented foods which have a proven effect, are not prohibitively expensive and for which no simple alternatives are readily available?

5.4 A precautionary regime

However, the distinguished nutritionist Arnold Bender advised caution in accepting health claims for functional foods because of the extreme difficulty of obtaining adequate evidence.[109] While epidemiological evidence sometimes implies that certain foods are associated with lower incidences of particular diseases, intervention studies have often been disappointing; and there may well be risks as well as benefits. For example, dietary fibre is widely advocated but when consumed in excess by some

104 See note 7, p.60
105 Jacobson M F and Silverglade B (1999) British Medical Journal 319, 205-6
106 Agerbaek M et al. (1995) European J of Clinical Nutrition 49, 346
107 See note 103
108 Bender A E (1998); see note 103, pp. 67-73
109 See note 108

individuals it causes intestinal discomfort and reduced absorption of zinc, iron and calcium. Analogously, in individuals carrying a gene for enhanced iron absorption, high iron intakes may prove toxic.

Bender noted that the "application of 'functional medicine' depends on knowing, as early as possible in life, the genetic susceptibilities of the individual." This is far removed from wholesale dosage of the public with a range of foods that may be beneficial to some but possibly harmful to others.

5.5 An ethical evaluation of functional foods

Our 'weighing' of the ethical impacts discussed above leads us to the following ethical evaluation of functional foods:

- **While functional foods present the prospect of promoting a healthy lifestyle for large numbers of people without resort to expensive medical intervention or prophylaxis, the severe limitations of such an approach need to be widely appreciated. (5.3.4)**

- **There are concerns that claims made by manufacturers may not always be scientifically established with adequate rigour or that they might only be effective in certain specific circumstances which occur only rarely. (5.2.1; 5.2.2)**

- **Some particular aspects of health which functional foods (or nutraceuticals) might be designed to address could be more readily, effectively and cheaply addressed by changes in the conventional diet or lifestyle. There is thus a need for health education programmes to promote public health through the most natural means rather than by resorting to 'medicalised' treatments. (5.2.2)**

- **Nevertheless, the concept of achieving health through dietary means is in principle commendable, and the marketing of reliable, affordable products which make a significant contribution to health should be encouraged. (5.3.3)**

6. THE WAY FORWARD

6.1 The Precautionary Principle

Pervading many of the considerations in this report is the notion of the Precautionary Principle (PP). The Principle does not imply that risks should never be taken (which might be termed 'precautionary paralysis'), but that in the absence of sound assessments of risks (and contingency plans for dealing with adverse impacts) it is both foolhardy and unscientific to proceed rapidly with the introduction of powerful new technologies.

While it is a characteristic of entrepreneurial activity that it involves taking risks, in the new world order, where not only the benefits of technological innovations but also their risks might have global implications, it is both prudent and ethical to proceed with more circumspection than market forces are inclined to allow. There is a genuine need, that is to say, to pay serious attention to the PP. Indeed, we believe that the PP should be established as a cornerstone of biotechnological decision making in relation to all agricultural and food systems.

"In its various legal forms [the PP] insists that where a substance or a technology is potentially damaging to the environment, regulation should be considered irrespective of final scientific proof"[110]. Applying it to the use of novel foods would appear to be an entirely logical extension of the PP, since it is clearly unwise to take serious risks which may jeopardise human, animal or environmental life or health. It needs to be recognised that although it may be possible to perform all sorts of experiments safely in controlled, confined conditions, we cannot, responsibly, 'do experiments on the environment'. Those who think otherwise must be considered naïve or rash.

In the present context, we believe that an expression of the PP needs to incorporate a number of specific concerns which arise from the ethical analysis of novel foods presented in this report.

In general terms, significant uncertainties about effects of novel foods on human safety and the environment (particularly in the case of GM crops which colonise the wider environment, but cannot be recalled if they cause adverse effects) suggest that there should be a presumption against their use unless good reasons can be advanced to overrule this. Such a principle ('No, unless') forms part of the legal regulation of genetic engineering in the Netherlands.[111]

It should be recognised than in referring to 'risks', we include not only threats to physical conditions, such as food safety, but

110 Parker J (1998) Precautionary Principle. In 'Encyclopedia of Applied Ethics' ed. Chadwick R. vol. 3. San Diego: Academic Press, pp. 633-641
111 See note 2

also infringements of principles such as 'consumer autonomy', 'biodiversity' and 'environmental sustainability' (with reference to the Ethical Matrix). None of the latter might necessarily cause direct harm, in the usual sense, but they are crucially important from an ethical viewpoint.

In assessing whether use of a particular GM crop should be licensed for growing, we believe due attention should be paid to whether the perceived problem addressed, or advantage envisaged, might be delivered by some alternative process which involves lower risks. Testing is itself problematical, and serious consideration needs to be given to the real-life circumstances in which novel foods are likely to be employed. For example:[112]

- the duration of observation may be inadequate to observe possible cumulative changes
- the end-points chosen for observation are limited by certain artificial requirements e.g. exclusion of birds
- although "demanding rules are imposed on crop management for the tests, no systematic assessments is made of the extent and consequences of real-world variation from these artificially tight behavioural conditions"
- the scientific assumption that GMOs act in complete isolation, without interaction with other independent agents, is highly questionable
- because of the complexity of the environmental interactions, significant effects could occur which are impossible to isolate causally as effects of the GMOs.

Food safety testing of novel foods also raises a number of questions which need to be more widely recognised by the general public and acknowledged by regulatory authorities. For example:

- scientific assessments can only investigate known hazards, so that risks like that of contracting CJD from BSE infected meat, now thought due to previously unrecognised infectious agents called *prions*, will not be addressed
- the concept of 'substantial equivalence' is of questionable validity since it relies on (limited) compositional analyses, which may fail to identify toxic components
- most risks diminish with decreasing level of exposure to the toxic agent, but since for many there is no threshold below which there is zero risk, the acceptable level is a matter of judgement, and hence, dispute
- the calculation of risk often depends on procedures of untestable validity, such as extrapolating risks to humans from experiments on animals, some of which are now known to have been totally inadequate in the past, e.g. in the case of *thalidomide*
- rarely are risks borne by the same people as those to whom the benefits accrue, so that (and for other reasons) benefits and risks are arguably incommensurable: e.g. is it, even hypothetically, permissible to equate potentially increased financial returns of agribusinesses with possible death and disability of consumers through food-borne diseases?

An additional problem, of major significance, is the speculative nature of cost/benefit analyses. Doubtless, the calculations which led to the inclusion of animal remains in cattle diets were considered economically sound - but in time they were proved to be disastrously wrong.

Moreover, we are concerned about the composition of 'expert committees', on whose shoulders rest responsibility for the safety of many millions. Risks are best identified when a wide range of expertise is involved in consultation and decision making. It is thus important to seek the opinion of *all* those with relevant expertise, especially those who dissent from the majority opinion (something that did not happen during the BSE crisis).

In our Recommendations (section 7) we incorporate these concerns as elements of the PP applied to novel foods. We believe that they are based on sound principles of both science and ethics; and that it would be profoundly unscientific, imprudent and unethical to proceed with a technology for essentially trivial reasons if its risks were undefined.

However, we stress that the PP should not be used as a (political) device simply to obstruct the vital contribution of technological innovation to modern civilised society. Luddite opposition to all technological development is as bigoted as the belief that all human problems are soluble by the application of 'technological fixes'. Rather, what is required is an approach in which technological inventiveness is tempered by a sensitivity to ethical concerns expressed within society, that displays a prudent recognition of human weakness (appreciating that even the strictest forms of regulation may be circumvented), and which has the humility to realise that 'we don't know what we don't know'

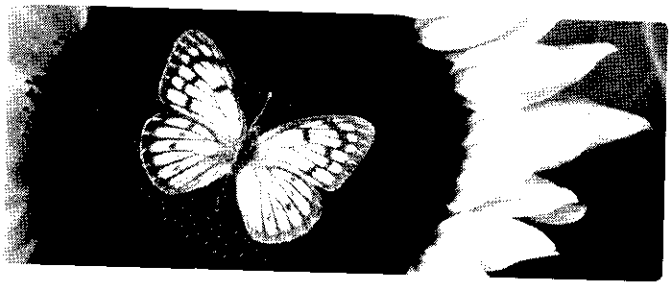
6.2 *Justifiable uses of GM*

The approach adopted in this report should not be interpreted as suggesting that we are opposed in principle to the techniques of genetic engineering. That would be a misconception, and we need to clarify our position on this point. While rejecting a naïve form of utilitarianism which equates the 'good' with a simple surplus of pleasure, profit or preference, we do recognise that many ethical decisions (if not most) involve some form of weighing of pros and

112 Wynne B (1999) in The Guardian (16.9.99), pp.S2-3

cons. It follows that if the potential gains were sufficiently great and the costs or risks sufficiently slight (and subject to other provisos concerning respect for autonomy, justice and wellbeing which are encompassed by the Ethical Matrix) certain potential applications might be deemed ethically justifiable.

While it would be difficult to prejudge such applications, it is possible to define the criteria of acceptability, as indicated in Table 2.



MORE ACCEPTABLE	LESS ACCEPTABLE or UNACCEPTABLE
Vital (e.g. for medical use)	Trivial (e.g. changing colour or flavour)
Using non-sentient organisms	Using sentient organisms
No non GM procedure exists or is being developed	Non GM procedures exist or are being developed
Very low environmental risk (e.g. by containment)*	Significant environmental risk (e.g. on biodiversity)
Negligible health risk	Significant health risk (e.g. allergens)
Culturally acceptable to the vast majority	Culturally offensive to a significant number
Compatible with sustainable food systems	Incompatible with sustainable food systems
Addressing the needs of the poor	Exacerbating the difference between rich and poor
Enhancing of farmers' autonomy	Encouraging farmers' dependence
Permitting choice	Restricting choice
Subject to democratic decision-making †	Introduced without public involvement

Table 2

More acceptable, less acceptable and unacceptable characteristics of biotechnology

*For * and †, see text*

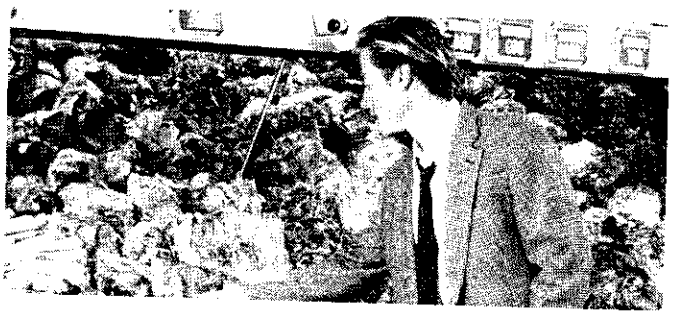
This form of check list is, in fact, merely a translation of certain of the principles presented in the Ethical Matrix (Table 1) in which we express our own normative convictions. Thus, the acceptability of 'very low environmental risk'* refers to 'respect for biotic conservation, biodiversity and sustainability' in the Matrix; the requirement for 'democratic decision-making'† to 'respect for consumer autonomy'.

The essence of the case presented is that the acceptability of any technology must be dependent on an appropriate ethical analysis, which might be facilitated by a framework such as that we have used in this report. The idea that such matters can be 'left to the market' is not a viable option in the complex, rapidly changing and highly interactive world in which we now live.

6.3 Need for investment in sustainable agriculture

An old joke, doubtless now politically incorrect, but nevertheless apt and perceptive, is the one that tells of the Irishman, who when asked 'the way to Dublin' replied 'Well now, if I wanted to go to Dublin I wouldn't start from here'. In truth, many of the debates about how we should act in future depend on different accounts of where we are now, and how we could get to the place from which we would like to start the journey to our, probably common, desired destination.

The Nuffield report appears to subscribe to the view that the better world we all seek can only be reached by 'more of the same' high tech solutions which have enabled large numbers of people to acquire unprecedented material wealth. And this might be thought the right path because, in the words of a spokesman for a leading biotechnology company: "If the rich don't buy it the poor won't get it".[113] This is a memorable sound bite, but one that jars when one considers that "there are now more people living in absolute poverty than ever before."[114]



113 Cited by Mepham, B (1999) Summing up and Future Prospects. Newsletter of the European Society for Agricultural and Food Ethics 1, 3-6
114 DFID (1999) Target 2015

A fundamental limitation in common perceptions of sustainability is that it is all about maintaining growth by increasing financial capital; i.e. the wealth of a society is measured in terms of the amount of money it has accumulated, or the buildings, possessions or marketable services which could be converted into money. Jules Pretty describes two other types of capital which are generally overlooked: Natural Capital (the stock of plants and animals and the ecosystems they make up, together with minerals, atmosphere and water) and Social Capital ("the structure of relations between actors that encourages productive activities").[115]

Pretty characterises Natural and Social Capital thus:

- they provide a basis for economic growth and enhanced human welfare
- they tend to be public goods and rarely have market value
- like 'club' goods they are indivisible
- they are diminished by external activities like factories or intensive agriculture, but the costs are borne by whole societies and ecosystems
- Natural capital is augmented if appropriate regenerative technologies are used
- Social capital is self-reinforcing, when exchanges increase reciprocity, and lead to greater trust and confidence.

In short, social wealth is built by developing social relations between people (not by increasing their dependence on anonymous providers of technology) and by employing regenerative production systems, which, for food, rely on biodiversity, soil fertility and natural resources (e.g. nitrogen fixation by leguminous crops).

Pretty points out that 50 years ago, at least half the money spent on food was received by farmers and the rural community. Now, with the food and drinks system cashing some US$ 1500 billion p.a., farmers typically get only 10-20% and pass on correspondingly less to their employees and rural communities.

The implications are clear: a world of GM crops would be a world dominated by the priorities of a handful of multinational companies. Unwittingly, uniformity could be imposed: natural and social capital degraded through disuse. Diversity is an essential element of sustainability, the vital reserves preserved for an unpredictable future. But diversity should not only be seen in terms of genetically determined biodiversity, important as that is. The richly diverse social components of the rural environment also need to be sustained and nurtured.

6.4 Justifiable uses of functional foods

It is necessary to draw a distinction between different types of functional foods. Nutraceuticals which are expressly designed to meet some perceived health problem, and for which there is acknowledged scientific evidence of benefit, would seem to be worthy of endorsement. Providing that transactions are transparent, with full disclosure of product information, norms of fairness need not be infringed by their marketing. But, if through lack of availability and/or cost, they are inaccessible to the most needy they will simply underline existing inequalities in healthcare provision.

However, the same commendation does not necessarily apply to all functional foods, which some consumers may erroneously view as technological fixes, capable of compensating for an otherwise unhealthy diet and lifestyle. This is a rapidly developing field and there appears to be an urgent need for government legislation to establish appropriate controls. A Joint Health Claims Initiative is in process of being ratified but "like most other non-binding, self regulatory efforts, it will probably bear limited fruit".[116]

6.5 A critical time in history

We are at a momentous point in history - and not merely because we are about to embark on the third millennium of the Christian era. More critically, the future of food could follow one or other of two radically different courses.

- GM foods, currently accounting for a very small amount of global food production, and virtually negligible outside the United States of America,[117] could provide increased yields of highly uniform food products by pursuing current trends in the intensification and industrialisation of agriculture on a global scale.
- Alternatively, food could be increasingly produced by organic and other sustainable systems, also currently providing a very small proportion of total food production, in which reliance on agrochemical inputs is drastically reduced and there is emphasis on sustainability, diversification and rural regeneration.

In the UK, and Europe more generally, public preference for the latter approach is reflected in a greatly increased demand for organic produce and a large-scale rejection of GM foods. Not only are there many unquantified risks associated with GM foods, particularly those related to environmental impacts and food safety, but many people are also wary of a food system which, because of its dependence on high technology, is inevitably shaped by the commercial imperatives of very few, very powerful

115 Pretty J (1998) The Living Land. London: Earthscan, pp 7-43
116 See note 105
117 In 1998, 74% of the global planting of GM crops (approx. 28 million hectares) was in the USA and 82% of the total area was devoted to soya bean and corn/maize. See N 2.44

multinational companies. The result could be that a handful of individuals (fallible, as we all are) could wield enormous power over the food supply to billions of people throughout the world.

Of course, it might be argued, the same applies to other commodities, like cars and electrical goods, whose supply is similarly controlled by very few individuals. But food is a unique consumer 'good' - it differs by being, literally, consumed ("We are what we eat"), whereas other commodities are merely used. Food is not only vital for human survival but, almost uniquely, its production both profoundly influences, and is influenced by, the biological environment in which it is produced. Moreover, the cultural significance of food is incomparable. Whatever opinion we may hold of the ethics of much food advertising, it often demonstrates the rich symbolic associations which exist between different foods and social norms and ideals. A reductionist conception of food, which views it principally in terms of nutrients or 'mouth feel', ignores its full significance. It may not thus be mere conservatism to oppose 'new-fangled' technology: rather, it may show a genuine concern for the cultural significance of food, which reinforces social bonds, feelings of worth and personal autonomy.

Such factors have no less weight in developing countries, and in certain respects more. The adoption of low labour high tech systems by countries requiring increased rural employment, less dependence on external inputs and more sustainable food production will not help but, more likely, hinder real development.

A significant hurdle to the introduction of socially and environmentally sustainable food systems is a conceptual inertia which can only envisage solutions to problems in terms of existing industrial technology. Because GM foods are, in one sense, 'business as usual', those who advocate them as a solution to problems of global hunger may take comfort in the belief that their worthy exhortations to apply 'hi tech' to needy causes are all that can, realistically, be done.

But ethics is not about placating the powerful in the hope that they might offer a few crumbs of comfort to the needy. It is about 'telling it how it is', uncomfortable as that might be. The reality is that a large part of the reason why the hungry are hungry is that others have too much - not just food but energy, material resources, health provision, etc. The average person in a developed country consumes and pollutes at vastly higher rates than those in less developed countries. That is to say "We cannot hope to uncover the root causes of hunger until we appreciate the degree to which economic policies pursued by the wealthier nations undermine the development of poorer nations". [118] Enabling the hungry to have sufficient will entail curbing the surfeits of those with excess.

A sustainable food system for all will not be easy to achieve. But it should be a secure system, building on indigenous knowledge and skills, life enhancing and respectful of diversity and cultural heritage. That is where investment is needed. In contrast, the way in which GM is currently being developed will exacerbate the current trend to increasing industrialisation of food production; a trend which is ultimately unsustainable.

7. RECOMMENDATIONS

7.1 Any application for the marketing of a Novel Food in the UK should be subject to a comprehensive ethical assessment of its potential socioeconomic and environmental impacts (in addition to the existing safety assessments) employing an agreed ethical framework, such as the Ethical Matrix used in this report (3.2). Advice should be sought from a broad range of expertise, including dissenters from the orthodox view.

The Ethical Matrix provides a framework for routine ethical analysis, use of which would ensure that due attention was paid to a comprehensive range of impacts of novel foods on all relevant interest groups. Because of the breadth of its remit, the expertise and experience of members of the relevant regulatory committees would also necessarily be broadly based. Critics of the orthodox viewpoint should be sought out, rather than shunned, since valid scientific theories will withstand the strongest criticism. Regrettably, in recent times, dissenters have often been ignored when they should have been listened to (as in the BSE crisis).

7.2 The time is opportune for a comprehensive review of agricultural aims and methods (e.g. encompassing GM, conventional and organic approaches). Ideally, such a review would be at the EU level, but given the current political will to modernise structures and attitudes, there is a clear opportunity for the UK to take the initiative with a national review. We believe that the current crisis in farming lends force and urgency to this recommendation.

The current developments in the use of GM foods are symptomatic of an approach to agriculture and food production that is significantly biased in favour of maximising commercial profits, especially and increasingly those of large corporations, rather than seeking optimal solutions to the problem of producing sufficient food in ways which are socially and environmentally beneficial.

118 See note 80, p.13

7.3 Close links should be established promptly between the UK's Agriculture and Environment Biotechnology Commission (AEBC) and the Food Standards Agency (FSA), both of which bodies are due to be set up in the near future, to ensure that the FSA benefits effectively from the strategic, including ethical, considerations which are the remit of the AEBC.

The AEBC will have a "wide-ranging remit including strategic analysis of biotechnological developments, addressing broader issues including ethical considerations regarding the acceptability of genetic modification, identifying gaps in the regulatory framework and building up a wider picture from the lessons learned from individual regulatory areas. It will work alongside the Food Standards Agency, which will take responsibility for all aspects of the safety of GM food".[119]

7.4 The Precautionary Principle (together with a comprehensive ethical analysis, as described above) should form the basis of the approval system for Novel Foods. With respect to applications for the growing of GM crops in the UK, the following elements of the Precautionary Principle are recommended:

i) The 'No, unless' principle should be adopted, i.e. the onus of proof of the acceptability of the proposal should lie with the applicant.

This requirement is justified by the problematical nature of novel, and particularly, GM foods. In particular, non-GM approaches should be given due consideration. For example, if the stated aim of a GM crop is to reduce herbicide use, the capabilities of alternative procedures such as integrated pest management (IPM) should be explored before granting a licence.

ii) 'Risks' should be taken to refer to impacts on the wide range of issues detailed in the Ethical Matrix and not simply those concerned with safety.

This underlines our view that 'scientific evidence' alone is inadequate. Public concerns extend to a range of transcientific issues (such as consumer choice and the sustainability of the rural environment, both physically and socially) which are not less important simply because they are difficult to quantify.

iii) More consideration should be given to the real-life circumstances in which GM crops might be grown

Conditions under which crops are monitored in scientific studies are unlikely to be replicated in commercial planting of GM crops. Assessments of the projected likely outcomes under real-life circumstances (e.g. by computer modelling techniques) should form an essential element of approval procedures. We believe there should be increased government funding for appropriate research.

iv) Any risks taken should be commensurate with anticipated potential advantages

Trivial objectives do not merit taking any risks, as defined under 7.4ii). By contrast, one can envisage that a GM nutraceutical with significant health benefits might merit a significant degree of risk.

7.5 If a GM food is awarded a licence permitting commercial growing in the UK there should be a legal requirement for long-term, independent, rigorous, monitoring of possible adverse effects (e.g. on biodiversity) and obligatory termination of the licence if pre-agreed thresholds are breached.

In terms of objectivity and public confidence, monitoring for possible adverse effects of GM crops cannot be left to biotechnology companies. A scheme needs to be instituted whereby companies pay a tax for independent monitoring, with the results being made publicly available.

7.6 Before any licence to grow GM crops is granted mechanisms should be in place to suspend authorization expeditiously and de-commission the site safely should thresholds be breached.

Appropriate procedures would be site-specific. Particular attention would need to be paid to risks which might be posed to neighbouring farms.

7.7 A system of compulsory liability for any adverse effects of GM technology on human health and the environment should be introduced, based on the 'polluter pays' principle.

119 Cabinet Office (1999) The Advisory and Regulatory Framework: report from the Government's review

A sliding scale of penalties relating to the severity of adverse environmental impacts needs to be drawn up prior to any authorisation of commercial planting.

7.8 The UK government should ensure that adequate and affordable non-GM food is available to consumers, at least until such time as it became clear that GM food was widely acceptable in society. This will entail increasing government assistance to farmers wishing to convert to organic and other sustainable forms of farming and increasing investment in scientific research in these areas.

The large scale rejection of GM foods in Europe, coupled with the increasing popularity of organic produce, provides an opportunity for a total reorientation of agricultural policy, so that the advantages of organic and other forms of sustainable food production, in terms of food integrity and quality, can be made more widely available, while also conserving biodiversity and nonrenewable resources and enhancing social amenity. The UK government has shown support for organic farming, most recently through the Organic Farming (aid) Scheme introduced in April, 1999. However, with 70% of the current UK demand for organic produce being imported, considerably more encouragement to convert, and support following conversion, is required.

7.9 Given the general dissatisfaction that many, including expert bodies, have expressed with arrangements for the safety assessment of GM foods (and, in particular, the limitations of the concept of 'substantial equivalence') we recommend that more resources are invested in furthering research in this area.

7.10 Given the general level of public concern over GM foods, we recommend the introduction of a system of compulsory labelling of all products of GM food technology, which is sensitive to consumer demand.

Forcing GM foods on a unwilling public would be as undemocratic as it would prove to be uneconomic.

7.11 There is a moral imperative for Western countries to increase their efforts to relieve hunger and poverty in less developed countries. UK government aid to less developed countries should continue to give primacy to poverty eradication and environmental sustainability, with a particular focus on the needs of the rural poor. Any proposals for application of GM crops in developing countries should be viewed with extreme caution because of their tendency to cultivate dependency, have adverse social impacts and undermine ecological stability.

While we do not categorically rule out the possibility that GM crops could play a role in less developed countries (e.g. were drought-resistant crops to become available), we advise the UK government to exercise extreme caution in promoting or supporting such innovations. Here, above all, the 'No, unless' principle is vital.

7.12 There is a need for the UK government to introduce legislation to control the imminent spread of functional foods, for which manufacturers may make health claims. Protection of the consumer from overambitious and unverifiable claims is a priority, while recognising that some such products could confer significant health benefits to some people if marketed responsibly and used appropriately.

APPENDIX I

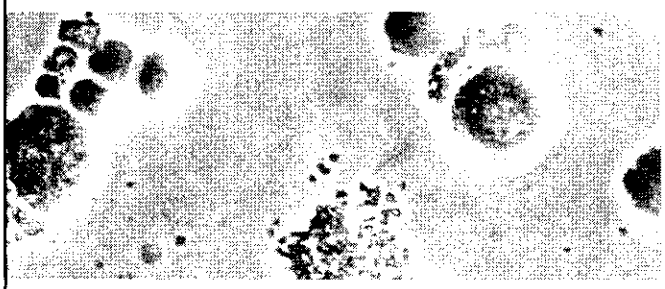
Summary of the questionnaire findings

A questionnaire was sent to 43 individuals involved in the debate on novel food. Sixteen questionnaires were returned, including strongly positive and negative views of GM foods and some mixed responses. Despite the poor response rate, the replies may be seen as valuable in that they reflect the diversity of opinion among some of the main protagonists in the field.

A general question about any improvements and/or harms which the introduction of novel foods might bring about in listed areas, was followed by a series of fourteen statements on issues of education and intervention, choice, information and marketing and global issues. Response was measured by a Likert scale from 5, agree strongly, to 1, do not agree at all, with 3 as neutral.

Seven statements were positive about novel foods and the producers ('the availability of novel foods is likely to benefit the consumer'), seven were either negative ('too much power is wielded by biotechnology companies') or could be agreed to by those with different views ('the nutritional standards of the public should be a matter of governmental concern'). In response to questions about the regulation of novel foods and whether the respondent had any 'intrinsic concerns' (sometimes classed as religious, moral or ethical) about novel foods or the ways they are produced', six replies were positive, six negative, while four had mixed responses.

There was space for comments on each section and we cite here a representative list of the comments received.



The possible and actual effects of novel foods

- Those arguing the possible benefits concentrated on the direct effects of the food itself:

- *Reduced mycotoxins in cereals, higher levels of vitamin E, delivery of vaccines in food, reduced pesticide residues in food; food safety; healthier grains.*

- *Yield to increase farmers' income which otherwise will fall steeply; to put back the micronutrients that plant breeding has removed. Free from fungal infection so safer. Quality - slower rotting and less waste.'*

- Those who took a negative view were concerned for wider issues as well:

- *Fundamentally this is about ownership of the food chain. It will not feed the world or help the planet. The risks to human and environmental health are huge and will increase. The process is also centrally involved in the patenting of life (and death) and will raise unpredictable but far reaching issues once Terminator technology becomes the standard form of patent protection for novel foods.*

- The mixed group gave similarly specific possible benefits, such as disease resistance and increased shelf life but also less specific possible harms such as:

- *unintended and unpredictable harms which cannot be properly managed and a chance of long-term harm to human health.*

One of the negative group commented on the vagueness of public concerns:

- *Although antis are condemned for 'scaremongering', the benefits are equally, if not more speculative. Jobs, competitiveness, increased nutritional value. What is the evidence? The public is NOT irrational - bring together all factors - multinationals, unpredictability etc.*

- All the anti group wrote that they had intrinsic concerns

about novel foods. The mixed group either had such concerns or wrote that they respected those who had. 'Intrinsic concerns' can also be seen as vague and perhaps irrational:

- *My objections are primarily scientific. However, my 'gut instinct' tells me this is a technology to avoid.*

- *I have [intrinsic concerns] only insofar as they [the producers] misunderstand the holistic nature of nature and pursue the dangerous/naive belief that science can produce progress without adverse consequences*

- Those who were positive about novel foods would not be expected to have intrinsic concerns although the respondent who was most positive cited an example where he would:

- *In extreme situations- yes. I would not eat an animal 50% human, 50% sheep. I imagine no one would.*

Information for consumers

The question 'who should take responsibility for deciding the amount and type of information to be provided for consumers?' divided the respondents between those who felt it was for the Government, the FSA, the ACNFP and industry and those who included consumers. Only one of those positive about novel foods mentioned any involvement for consumers with the answer:

- *Government. Consumer driven otherwise it will not be taken seriously by the public.*

- For the antis and mixed group, consumers were included either in consultation with Government or Government consulting consumers. Three respondents mentioned the need for European or International governments to be responsible. One specifically mentioned the need for an EU Commission and Parliament:

- *to secure a level playing field and stand up to the US.*

The anti group mainly supported 'detailed labelling' although one respondent wrote that

- *labelling is hopeless if all foods are labelled GM and you want GM-free.*

- Those who saw novel foods as beneficial also tended to see labelling as necessary for consumer confidence:

- *Giving the consumer the ability to avoid GM food if required should be paramount.*

However, another argued that although it was important for the public to be confident, introducing a novel food was simply one of many changes made to food production each year and

- *The public does not demand the right to know about each one. Maybe each food needs an http address which really tells you where it comes from.*

Regulation and public education

For those with a positive view, public unease about novel foods was due to a lack of understanding of the science and a lack of confidence in the regulatory mechanism. They agreed that the proposed FSA should have final responsibility for the safety, quality and efficacy of novel foods, seeing strict procedures as the way forward:

- *A more rigorous testing procedure may be advisable to minimise public concern and it needs to be very tough to start with to restore public confidence.*

- Those with negative views were either unsure or disagreed with the FSA as regulator. Their doubts were to do with its composition, degree of accountability and openness. While agreeing that the public might have 'considerable misconceptions' about the science of genetics, those with concerns about novel foods felt that these would not be alleviated by more education because:

- *the more the public is educated the more concerned it will become.*

One respondent pointed out that there is contradictory evidence as to the effects of more public education. Certainly, scientifically informed respondents were to be found arguing both for and against novel foods.

- A straightforward question on current regulations by which 'if foods can be shown to be substantially equivalent (on a physico-chemical basis) to existing products, no further regulation is required' asked 'Do you consider this approach to be sufficient?

The supporters of novel foods answered *'yes'* although two felt that more testing was needed because of public concern rather than because it was necessary. The opponents answered *'no'* and described 'substantial equivalence' as:

- *'scientific nonsense', 'unscientific' and 'an attempt to defraud the process of proper public/scientific scrutiny'.*

Effects on the developing world

Two statements about the effects of novel foods on the Third World were put in a way that was positive to biotechnology:

- Concerns over safety may hinder developments which could benefit Third World countries

- Feeding the world should be the priority and biotechnology seems to offer the best hope of doing so

Those who saw no benefits from novel foods did not agree at all with the statements. They gave priority to feeding the world but argued that biotechnology would be more likely to harm rather than help and that the developing world did not want it. For them, the development of biotechnology would not benefit consumers but the companies holding the patents. The positive group all agreed with both statements but either made no comment or, in two cases, pointed out that the problem of world hunger could not be solved by biotechnology alone. Those with mixed views tended to think the technology might not be relevant to the Third World:

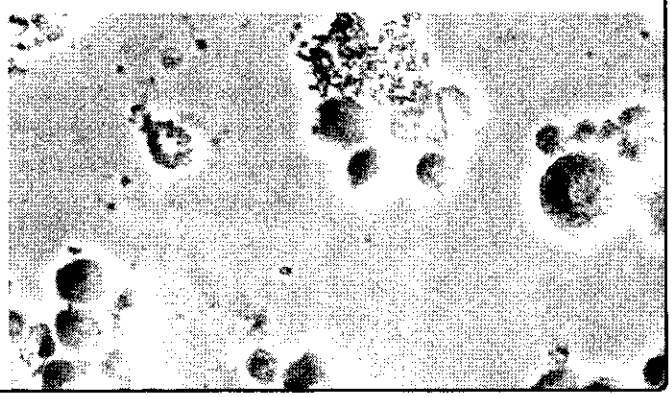
- *I doubt that the currently available GM products will have an impact on production or consumption outside the developed countries*

- *There are other possible ways in which food production might be improved*

Summary

A group of informed respondents did not agree on whether novel foods are safe, their effects on the environment and on developing countries or on the means to regulate them. The distrust between opponents and supporters of the technology was mutual. Among those positive about novel foods there was frustration that what they saw as a safe and well regulated technology was opposed by a public who need more understanding to be able to take part in the debate and by *'NGOs with an axe to grind'*. Opponents of novel food claimed that producers, retailers and scientists employed in the research have vested interests in its success and that unknowable long-term effects and intrinsic concerns cannot be addressed simply by labelling or testing. One supporter of novel foods wrote:

- *The recent debate has so polarised people's views that it is difficult to see how current concerns can be effectively addressed.*



APPENDIX 2

We are most grateful to the following for their co-operation when we were preparing the report (in responding to the questionnaire and/or in other ways). Those named do not, of course, necessarily endorse the report's analysis or recommendations

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Prof Robin Grove-White, University of Lancaster

Prof Brian Goodwin, Schumacher College

Dr David Heaf, IfGene

Prof Jonathan Jones, John Innes Institute

Prof David Ledward, University of Reading

Dr Sue Mayer, Gene Watch

Lord Peter Melchett, Greenpeace

Dr Erik Millstone, Sussex University

Prof Jules Pretty, University of Essex

Rev Dr John Polkinghorne, University of Cambridge

Rev Dr Michael Reiss, University of Cambridge

Dr Michele Sadler, Institute of Grocery Distribution

Ms Julie Sheppard, Consumers Association

Mr Andrew Simms, Christian Aid

Mr Alan Simpson MP, House of Commons

Mr Colin Tudge, Author and broadcaster

Dr Greg Tucker, University of Nottingham

Mr Paul Tyler MP, House of Commons

APPENDIX 3

FOOD ETHICS
COUNCIL
THE INDEPENDENT COUNCIL FOR ETHICAL STANDARDS IN FOOD AND AGRICULTURE

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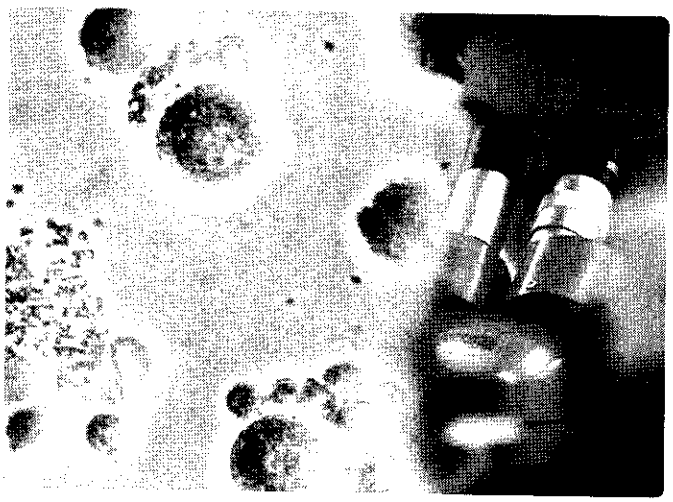

ACRONYMS used in the report

ACNFP	**Advisory Committee on Novel Foods and Processes**
ACRE	**Advisory Committee on Releases into the Environment**
BMA	**British Medical Association**
Bt toxin	**An insecticide produced by a bacterium *Bacillus thuringienis***
DFID	**Department for International Development**
FDA	**Food and Drug Administration (USA)**
FSA	**Food Standards Agency**
GM	**genetically modified**
GMO	**genetically modified organism**
HRC	**herbicide resistant crop**
IPR	**Intellectual Property Rights**
MAFF	**Ministry of Agriculture, Fisheries and Food**
PP	**Precautionary Principle**
R&D	**research and development**
SE	**substantial equivalence**