# Keeping the Balance

## Policies on Genetic Modification

**Policy Paper 31**

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# Introduction

1.0.1 In 1993, the Liberal Democrats were the first British political party to produce a comprehensive policy statement on genetic modification, entitled *The Challenge of Genetic Engineering*.

1.0.2 In October 1998 the Party decided to commission a further Working Group to look again at this rapidly progressing field. The intense public concern over the development of genetically modified crops and foods in recent months shows that once again the Liberal Democrats were at the leading edge of political debate.

1.0.3 This paper builds on the sound foundation laid by *The Challenge of Genetic Engineering.* Inevitably it focuses more strongly than the previous paper on the issue of GM crops and foods, which is the subject of most intense current concern. Medical applications of genetic modification are nevertheless of enormous importance and are addressed, together with issues raised for patent law and international trade regulation.

1.0.4 In approaching the difficult questions raised by this new technology, the Working Group has striven to apply basic Liberal Democrat principles. This has not always been easy, as there are some inevitable tensions between competing but equally valid considerations. In particular, the preamble to the Liberal Democrat constitution commits us both to safeguarding the balance of nature and the environment, and to harness technological change for human advantage. Other well established Liberal Democrat principles which are highly relevant include the need for openness and accountability in government decision-making and regulatory procedures, and the rights of individuals to make informed choices over their own lifestyles. We are also conscious of the need for British and European agriculture and industry to compete internationally, and do not wish to create unnecessary burdens which would compromise their competitive position.

1.0.5 Undoubtedly there are significant commercial, health and environmental benefits which may be achieved through the responsible application of genetic modification techniques. There are nevertheless many concerns about potential risks associated with genetic modification. It is therefore essential that we have the correct public policy framework in place to ensure that public concerns are met before commercialisation takes place, and that in any areas where it does go ahead the technology is used responsibly.

1.0.6 In particular we support the precautionary principle, which is endorsed as the basis of EU environmental policy by Article 130r(2) of the European Communities Treaty. This principle requires that where there is a threat of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. We are also attracted by the 'step-by-step' approach to implementing the precautionary principle advocated in the European Directive on deliberate release of Genetically Modified Organisms (GMOs), 90/220/EEC; under this approach 'the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken.'

1.0.7 We have also considered whether the risks involved in genetic modification are so qualitatively different from other technologies as to require a specific body of law and regulation. There are risks associated with any process for creating or introducing novel products or organisms, and it is true that some non-genetic developments, such as the introduction of non-native species or the move to winter wheat, have had serious adverse effects on biodiversity of the kind which critics of genetic modification fear. Nevertheless, genetic modification is a departure from more traditional selective breeding methods as it permits gene transfers across barriers of sexual compatibility, allows them to occur within greatly reduced timescales, and heightens the risk of producing novel genes. However, it is also much more specific in the selection of genes than breeding methods. We conclude that it is appropriate that there should be specific measures taken to regulate genetic modification; and it is expeditious to consider some wider issues raised by genetic modification at the same time, even where equivalent problems can exist in a non-GM context.

1.0.8 The key recommendations of the paper include:

- Maintaining the five year moratorium on commercial growing of GM crops adopted as Party Policy in September 1998, to allow time for current government funded research projects on the long-term environmental and health consequences of commercial growing to be completed, and for a full and well informed public debate on the issues.

- Strengthening labelling requirements to ensure that any product or ingredient produced through genetic modification is clearly so labelled

- Requiring mandatory segregation of GM crops at source

- Imposing a statutory legal liability without time limitation on the producers of GM products for any adverse health or environmental effects

- Enhancing the openness and breadth of representation of regulatory and advisory bodies

- Outlawing patenting of genes

- Upholding the existing bans on human cloning or germ-line gene manipulation

- Creating an Animal Protection Commission which would advise existing regulatory bodies on animal welfare and husbandry issues relating to transgenic animals

- Calling for reforms to the World Trade Organisation agreements as part of the 'Millennium Round' to allow for greater account to be taken of environmental, animal welfare and public health considerations

- Legislating for strict confidentiality in relation to genetic information held on individuals, and preventing insurance companies requiring genetic screening

1.0.9 We also recommend that should clear evidence emerge that commercial growing of GM crops will inevitably cross-pollinate organic crops, the Liberal Democrats should urgently consider the appropriate policy response (see 4.3.1).

1.0.10 We recognise that many of the recommendations in this paper will require action or legislation at the EU level, and will have to be negotiated with our European partners. Liberal Democrat MEPs will have a crucial role in advancing this agenda through the European Parliament.

# What is Genetic Modification ?

2.1.1 When a new plant or animal is created by pollination or mating, or when a micro-organism divides, the blueprint that must be followed to make the new offspring is transmitted. It was in 1953, when Crick and Watson discovered the structure of Deoxyribonucleic Acid (DNA), that the mechanism for this transmission was understood for the first time.

2.1.2 The structure of DNA is that of two long strands of atoms helically interwoven. Each strand consists of sequences of four chemical units (bases) repeated along its length. The order of the bases on one strand determines the order of the bases on the other strand. When cells divide to construct new individuals the DNA in the cell is 'unzipped'; one half going to each new cell. The single strands then re-construct their other halves.

2.1.3 The order of the bases on the DNA is the genetic code of the animal, plant or micro-organism. The entire code of the organism is called its genome. All the information for a whole organism is transmitted in all the cells but only parts of the code are expressed (that is, activated) in any one cell. In higher animals and plants, the DNA is organised into several larger structures called chromosomes, which can easily be seen using microscopes.

2.1.4 Particular characteristics of an organism are associated with only small regions of DNA which have specific places on identifiable chromosomes. These regions are called genes. If expressed in a particular cell, each gene gives to that cell a specific property; for example, the cells in the human pancreas are able to make insulin because there is a specific gene on one of the human chromosomes which tells the cells how to produce it. If that gene were to be removed, the cells would cease to have that ability.

2.1.5 Genetic modification is a technique, or rather a number of techniques, which allow particular genes to be located on the chromosomes of one organism, clipped out and spliced into the DNA of any other organism. Thus it enables genes, and hence their abilities, to be transferred across species boundaries.

2.1.6 However, the processes involved in genetic modification are not exact. While the precise sequence of genes intended to be introduced into the host organism is known, the position of insertion is not generally known. The number of copies of the insert introduced into the genome cannot currently be controlled during the insertion process. The characteristics of a Genetically Modified Organism (GMO) cannot therefore be determined with absolute certainty in advance, and have to be identified by subsequent testing. Of course, the characteristics of new breeds produced by conventional selective breeding are also unpredictable.

# Genetically Modified Crops

## 3.1 Potential Consequences of GM Crops

3.1.1 Those who support use of GM crops cite a series of potential benefits. These include:

**Improved yields:** Insertion of new genes can be used to introduce new traits in crops resulting in better yields, for example by enhancing resistance to frost, drought, pests or herbicides. In one case, work is taking place on transferring a rice gene which gives protection against nematode worms to other vegetables, such as the potato. The introduction of marker genes can help warn of the onset of plant diseases by making leaves change colour.

**Environmental protection:** It is argued that the introduction of GM crops will reduce the use of pesticides, as pest-resistant varieties require less spraying. Increases in yields may also reduce the pressure to bring as yet uncultivated land into agricultural use.

**Consumer benefits:** GM crops can produce foods with a variety of advantages to the consumer. For example, some GM tomatoes ripen more slowly, resulting in a stronger flavour and greater firmness. Longer shelf-life and greater uniformity could lead to lower prices. GM foods may also give dietary benefits, for example oils which contain lower levels of saturated fat, and high-starch potatoes which absorb less fat when fried.

**Industrial applications:** GM crops have a wide range of non-food applications. Work is in progress on a paper pulp tree with modified lignin which is aimed at helping produce paper using less energy and bleach, and there are already in development plants which can assist in reclaiming industrial land by extracting metals from the soil.

**Helping the developing world:** Advocates of GM crops believe that they can be of particular benefit in improving agricultural production in the developing world, for example by widening the range of climates in which crops can be grown or increasing salt or drought tolerance.

3.1.2 Critics of genetically modified crops point to a number of potential risks:

**Genetic cross-pollination:** There is a risk that cross-pollination may occur between GM and non-GM crops, and opponents of GM argue that potential adverse effects might flow from such cross-pollination. The Soil Association is concerned that cross-pollination will undermine the viability of organic farming, as their definition of organic food requires it to be GM-free. Organic honey producers have expressed particular concern. There are also concerns that cross-pollination might threaten bio-diversity, for example by giving rise to herbicide-resistant weeds which could disrupt the ecological balance.

**Environmental damage:** It is argued that far from reducing herbicide use, the introduction of resistant crops will tend to increase the use of herbicides. This in turn would reduce the numbers of wild plants and animals, threatening biodiversity. The introduction of GM crops may also increase the existing trends towards specialisation and monoculturalism, threatening the loss of many traditional crops. Critics see GM crops as simply an extension of intensive agricultural practices.

**Pathogen risks:** There are concerns that the use of therapeutic antibiotic marker genes in GM crops to identify which plants have adopted the inserted trait may lead to the transfer of antibiotic resistance genes to bacteria. This has potentially significant implications in regard to the use of antibiotics in both human and animal medicine. There are also concerns arising from the use of modified viruses to generate viral resistance in plants.

**Economic and social effects:** There is already a high degree of consolidation in the agrochemical/seed industry - higher than that in the pharmaceutical sector, for example. It is feared that genetic modification may lead to large parts of the food chain being dominated by a few companies, with potential for the abuse of a dominant market position. Some are particularly concerned that farmers in developing countries may be compelled to buy seed annually from seed companies as a consequence of the use of 'terminator gene' technology.

**Human health risks:** There are concerns that the allergenicity and toxicity of GM foods may be less easily identified than with conventional foods. There has also been little research into the long-term effects on the human body of consuming GM products - as yet no human trials have taken place.

3.1.3 In addition to the unfolding debate among scientists, environmentalists and industry, we cannot ignore the very strong mood of concern and uncertainty with respect to GM crops and foods among the general public which has developed in recent months, expressed in the letters pages of newspapers and in the formation of new pressure groups. Coming close after the BSE crisis, it is perhaps not surprising that there is considerable resistance to novel sources of food. Achieving a level of public acceptability will be a serious challenge for the developers of GM products.

## 3.2 Balancing Risks and Rewards

3.2.1 Some of the claims made for the benefits of GM crops are still unproven. It is not clear whether herbicide use will rise or fall following the introduction of GM crops - the UK government is conducting a review of this question through the Pesticides Safety Directorate; and we are not convinced that genetic modification offers a ready solution to the problem of world hunger, which is primarily a result of economic and political factors, although GM may have a role to play in boosting developing country food production. Despite these caveats, GM offers many advantages in terms of increased yield, consumer benefits and industrial production, and perhaps environmental benefits also.

3.2.2 Equally, while some of the alleged risks of genetic modification are speculative, there are many widespread concerns, including the possible impacts on organic farming, antibiotic resistance, pesticide use, reduced biodiversity, the consequences of long-term cumulative effects, and the fact that it may prove difficult or impossible to recall GMOs once released into the environment.

3.2.3 It is therefore prudent to proceed cautiously in the development and exploitation of genetically modified crops, adopting the precautionary principle and the step by step approach outlined above, assessing environmental and health risks at each stage of development.

## 3.3 Regulatory Framework

3.3.1 Any company, research institute, or university wishing to undertake field trials needs approval through the Department of the Environment Transport and Regions from the independent body ACRE, (the Advisory Committee for Releases to the Environment). ACRE itself is supported by a number of specialist committees and

technical sub-committees. ACRE requires a scientific explanation for any GM trial, and a detailed risk assessment. If approved, the size and location of the plot, timescale, and limitations, for example on borderwidth and disposal of the crop, are specified. Since February 1992 all details have been available on public registers under directive EC/90/220. ACRE is also the 'competent authority' under the directive, which considers commercial planting in the EU. Each of the 15 competent authorities examines every proposal. If agreement cannot be reached a decision is taken by the Commission under qualified majority voting. Only one GM crop is currently grown commercially in the EU. In 1998 10,000 hectares of GM maize were grown in Spain and 1,000 hectares in France, although French approval has since been withdrawn.

3.3.2 In addition, there is a second independent advisory committee, ACNFP (the Advisory Committee on Novel Foods and Processes) working via MAFF to fulfil the requirements of EC Novel Food Regulation 258/97. Whereas ACRE is primarily concerned with the impact of GM crops (and other matters) on the environment, ACNFP is concerned with the safety of GM (and other novel) foods that we eat. Of the 11 current members, one is a consumer representative and another an ethicist. In considering its decisions it takes advice from the DETR and Department of Health.

3.3.3 The Government recently announced their intention to set up a new strategic advisory commission to cover the use of biotechnology in agriculture and its environmental effects. It will operate alongside the Food Standards Agency. (which will act as the strategic advisory body for GM foods when set up), and be answerable to the Minister for the Cabinet Office who is chair of the Cabinet Committee on Biotechnology and Genetic Modification. As neither the proposed Commission nor the Food Standards Agency are operational at the time of writing, it remains to be seen how effective they will be in dealing with some of the fundamental issues already raised.

3.3.4 Also relevant is the Advisory Committee on Animal Feedingstuffs (ACAF), which is in the process of being set up, and will in the short term report to both MAFF and the Department of Health. This will have the task of assessing the safety of GM animal feeds, including protecting human health. There are concerns that the testing of such feeds is not conducted on a sufficiently long-term basis.

3.3.5 As GM crops reach the stage of commercial growing in the UK the responsibilities of ACRE and ACNFP will increasingly overlap. The government has recognised this and following statements by Michael Meacher and Jeff Rooker on 21st October 1998, a new Ministerial Group on Biotechnology and Genetic Modification was set up, chaired by Jack Cunningham. There is also talk of a possible environmental stakeholder's forum. At the same time it has been recognised that ACRE needs to look much more widely at the indirect environmental impacts of new crops. For example, if insect resistant plants affect the number of insects who used to feed and be killed on the previous plants, what happens to the insects who feed on them, and the birds that feed on them both? ACRE established a technical sub-group on 15th March 1999, which includes a pesticides expert from English Nature and the director of conservation at RSPB, to look at these wider impacts. A second sub-group is to look at the best strategies to minimise the impact of GM on the environment. The Government recently concluded that it should be for Ministers to decide the most appropriate balance of lay representation on regulatory committees in each case.

3.3.6 We believe that these bodies form a good basis for regulation of GM crops. We recommend the following improvements:

- Their composition should be broadened to include a mix of consumer, lay, farming and scientific interests

- Their meetings should be public, but with provision for specific commercially sensitive matters to be dealt with in closed session

- All members should register their financial and other relevant interests. Members with business interests in genetic modification should not vote on any decisions which are directly related to projects, enterprises or organisations in which they have an interest
- All trials of GM crops should be independently verified, and ACRE, ACNFP and ACAF should have their own full-time staff able to perform this verification

- A significant proportion of the costs of trial verification should be recouped by a charge on the commercial enterprises that would benefit from the verification process

- The House of Commons Environmental Audit Committee should be given the explicit remit to scrutinise appointments to ACRE, ACNFP, ACAF and the proposed advisory commissions, and to monitor the co-ordination of GM matters within government

- Procedures for the assessment of animal feeds must be improved

- The new Food Standards Agency should take on overall responsibility for co-ordinating the work of these bodies, and for considering any gaps in the structure.

3.3.7 The recently proposed voluntary guidelines on growing GM crops by the industry group SCIMAC (Supply Chain Initiative on Modified Agricultural Crops) are welcome, but we are concerned that they will not be compulsory, may suffer from poor take up and low awareness within industry, and that compliance may not be effectively monitored by independent assessors. A further criticism is that the guidelines appear to take little account of environmental considerations.

## 3.4 Legal Liability

3.4.1 The principle of legal liability could also play a part in clarifying responsibility and ensuring that promoters of GM crops behave prudently. It is right than any person suffering harm, whether to health or the environment, through the negligence of the regulatory bodies or GM companies should be entitled to full compensation. In this context, it is to be borne in mind that any adverse consequences of genetic modification may not become apparent or provable for a considerable time. We therefore propose:

- A statutory duty of care to be placed on the regulatory bodies, companies producing and selling GM products, and those using them for commercial purposes

- No time limitation for bringing cases under this legislation

## 3.5 The Case for a Moratorium

3.5.1 Research on many different GM crops has been carried out in the laboratory and in small scale plots. However, a major criticism of the research to date is that very little has been done to assess the likely impact on birdlife, biodiversity and other environmental matters from widespread commercial growing. The DETR has established a programme of farm scale trials due for completion in 2003 to examine these questions. Specific projects include work on the environmental impact of insect resistance in GM plants, on the impact of multiple tolerance in GM plants, and on monitoring large scale releases of GM plants. In accordance with the precautionary principle, we believe that

these projects should be completed and assessed before any commercial growing of GM crops in the UK is permitted.

3.5.2 As noted in 2.1.3 above, there is also considerable public anxiety about GM farming. Even if the risks of GM crops could be shown to be minimal or non-existent, it would be unwise to proceed quickly with large scale growing of GM crops in the British countryside in the face of widespread public concern.

3.5.3 We therefore re-affirm the policy, adopted by the Liberal Democrats in September 1998, of a five-year moratorium, preferably at the EU level, on commercial growing of GM crops in order to assess the possible impacts on the environment and biodiversity.

3.5.4 Two main tasks have to be undertaken during the moratorium. The first is to perform the necessary research and testing to allow well-informed decisions to be made at the end of five years on the risks and benefits of GM crops, so that the case for moving to commercial growing can be fully assessed. This will involve both laboratory and field trials, and further research on human health effects. We believe that the controls on field trials need to tighter than at present, and in particular:

- There should be genuine advance public consultation in localities where field trials are proposed, which should take into account any local plans for conversion to organic farming
- Field trials should not take place near to farms growing species that could be adversely affected by cross-pollination
- Existing guidelines on isolation distances are not sufficient, and should be amended upwards
- The environmental impact assessment should be performed by independent assessors, not by the company running the trial

3.5.6 The second is to use this time to facilitate a well-informed public debate on the issues raised by GM crops. Government can assist in this process by supporting public education initiatives from a wide spectrum of organisations, including for example NGOs representing environmental, consumer and other concerns, as well as scientific organisations such as the British Association for the Advancement of Science. We also believe that the recent controversy points up the need for stronger science teaching as part of basic education, including in particular the ability to assess and weigh risks and hazards.

3.5.7 If a decision is made to proceed with commercial growing of any GM crops after the moratorium period is completed, there will remain a need for an independent post-approval monitoring programme for a considerable period - the NFU has suggested ten years. Continued licensing of the crop should be dependent on satisfactory findings from the monitoring programme; adverse findings should result in the immediate withdrawal of approval.

## 3.6 Other Recommendations

3.6.1 The risks of creating antibiotic resistance in bacteria associated with the use of antibiotic marker genes were noted in 2.1.2 above. As there are alternative marker techniques available, we propose:

- The swift phasing out of the use of antibiotic marker genes

3.6.2 Many of the environmental concerns over GM crops apply equally to intensive agriculture generally. Liberal Democrats support an overall policy framework which will reduce the pressures on farmers to go down the intensive route. In particular, we will reform the Common Agricultural Policy by introducing a system of Countryside Management Contracts - a targeted system of direct payments to support environmental, economic and

social goals in rural communities, including conversion to and support for organic farming.

3.6.3 In the event that commercial growing of GM crops is allowed to proceed, agricultural biodiversity may be diminished. It is essential that seeds from the widest possible variety of crops are maintained in seed banks, so that varieties not presently cultivated are not lost for ever.

3.6.4 The growing market dominance on a world scale of certain agro-chemical companies, a development which is likely to be reinforced by genetic modification, is the subject of legitimate concern. We therefore support:

- Inclusion of global competition issues in the forthcoming renegotiation of the WTO, the so-called 'Millennium Round'

3.6.5 In a recent joint report, the government's Chief Scientific Adviser and the Chief Medical Officer recommended the establishment of a national surveillance unit to monitor population health aspects of GM and other novel foods. While welcoming this proposal, it should not take the place of more rigorous safety testing before products are allowed into the food chain.

# Consumer Choice in Foods

4.0.1 Liberal Democrats hold to the principle that citizens should be able to make informed choices over their own lifestyles. This clearly includes decisions about what types of food they eat. The general principle is re-inforced by the obvious reservations of many consumers about buying GM products, which has been acknowledged by the policies of leading retailers and food manufacturers. The right to know whether foods contain material from genetically modified organisms, or have been produced using GM techniques, is one which we advocate. The two key elements to preserving consumer choice are clear labelling and crop segregation.

## 4.1 Labelling

4.1.1 Some foods, such as oils and sugars produced from GM crops, contain no trace of the inserted gene which was present in the source plant. Other foods, especially those containing GM soya, do contain detectable GM material. Because the EU labelling laws which came into force on 1st September 1998 require labelling only if GM material can be detected after processing, and then only if it exceeds a threshold level, the vast majority of products which contain ingredients from genetically modified plants will not be labelled to that effect. Hence, consumers could be buying products from GM plants inadvertently, which may be unacceptable to consumers who have a general ethical objection to genetic modification in addition to any direct health concerns. We therefore propose:

- Amending EU legislation to require clear labelling of any product that contains ingredients produced as a result of genetic modification.

## 4.2 Segregation

4.2.1 In order for consumers to have the option of choosing between GM and non-GM foods, there must be segregation of the two at all stages of production and distribution. This means growing GM crops in separate fields, separate harvesting and storage of GM crops, and for processed foods separate manufacturing facilities.

4.2.2 A number of commercial organisations have already decided in response to consumer wishes to require segregation of GM crops from their suppliers. We wish to go further and make segregation of GM crops a legal requirement. We therefore support:

- Mandatory segregation of GM crops at source and in all subsequent stages of the production and distribution chain.

## 4.3 Organic Food

4.3.1 Organic food is growing in popularity, and we wish to preserve the right of consumers to choose organic produce if they so wish. This freedom is potentially threatened by GM farming if cross-pollination from GM crops proves to be an insuperable problem. The five -year moratorium we propose is designed in part to allow for research to determine the risks of cross-pollination. We may at the end of this period find that there is an unavoidable choice to be made between the competing claims of consumers who wish to purchase GM products, and those who wish to eat organic food. Although we do not wish to pre-judge that decision now, we consider that if and when it becomes apparent that such a choice has to be made, the Party should without delay have a full debate and

reach a policy decision on the point. That would be consistent with our political lead in this area, our commitment to full democratic debate of difficult and controversial issues, and gives respect to those within the Party and society as a whole who wish to continue to consume food which does not contain any genetically modified ingredients.

# Intellectual Property and International Trade

## 5.1 Patenting Genes

5.1.1 Intellectual property rights in the field of genetics raise important questions, both for food and medical applications. Patenting of DNA sequences is controversial. Can the isolation and description of a sequence legitimately be described as an invention or is it simply the discovery of an existing entity ? Given the conventional requirement for a patent to be issued - novelty, non-obviousness, and utility - the argument that a DNA sequence, or even a sequence with a function ascribed to it, or even one with a use proposed for it, meets these criteria is clearly questionable.

5.1.2 The EU has sought to settle this matter through its *Directive on the Legal Protection of Biotechnological Inventions*. As amended, the directive rules out patenting of the 'simple discovery' of a human DNA sequence, or other body parts, but it does not seem to do so explicitly for other organisms. It permits the patenting of human DNA sequences where the application meets the criteria for normal patenting, but also states that 'an element isolated from the human body or otherwise produced by a technical process which is susceptible of industrial application is not excluded from patentability even if it is identical to that of a natural element.' This seems to be weaker than normal patenting criteria, and is justified on the basis that the patent system provides insufficient incentives for research in biotechological medicines.

5.1.3 Another linked issue is farmers' ability to save seeds. The directive allows farmers the right to save seeds.

5.1.4 We take the view that simply decoding a genome, human or otherwise, is an exercise in discovery rather than invention. We oppose the granting of patents over genes themselves. Patents should be granted only for particular applications or techniques involving genes. This would mean that once a particular use for a gene had been patented, it would still be open to other researchers to develop and patent other uses of the same gene without having to seek permission from or pay royalties to the original patentee. We recognise that this will involve renegotiation of the Directive. Accordingly:

- Patenting of genes should be prohibited

## 5.2 Biodiversity and the TRIPS Agreement

5.2.1 The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), one of the treaties overseen by the World Trade Organisation (WTO), sets minimum standards for protection of intellectual property rights for all signatory states, and makes it easier for a patent registered in one country to be registered in other states. The TRIPS Agreement is enforced through the powerful dispute settlement mechanism of the WTO.

5.2.2 Article 27 of the TRIPS agreement does allow scope for countries to deny patentability of inventions in order to protect public order or morality, human, animal or plant life, and prevent serious harm to the environment. The WTO record in dealing with disputes, however, indicates that it prioritises trade over environmental considerations, and it requires a strict proof

of necessity in order to bring the exemption into play.

5.2.3 The TRIPS system also exacerbates fears that transnational corporations may be able to use their intellectual property in GM products to establish world monopolies, and that they may be able to exploit the natural heritage of developing countries with no benefit flowing back to the countries of origin of the genetic material. If a useful plant is located in a rainforest or elsewhere, it might be used to manufacture a new product which could be patented and then sold back to the original country.

5.2.4 The subject of 'bio-prospecting' was addressed in the 1992 Convention on Biological Diversity (CBD). Article 15 of the CBD requires signatories to seek permission before prospecting for genetic resources in the territory of another state, and provides for agreements to share equitably the results of any subsequent commercial use. Article 16 also calls for the transfer of genetic modification technology to developing countries to help them make use of their own genetic resources. However, the USA is not a signatory to the CBD, and unlike the WTO the CBD does not have effective dispute settlement mechanisms and is largely unenforceable.

5.2.5 We call for:

- All countries to sign the Convention on Biological Diversity, and for it to be given effective enforcement powers
- Issues concerning TRIPS and genetic patenting to be reviewed as part of the WTO 'Millennium Round'
- The creation of an international stakeholders' forum to consider how intellectual property law needs to respond to the issues raised by genetic modification

## 5.3 International Trade in GMOs

5.3.1 The freedom of individual countries to restrict imports of GM products is limited by the WTO. Article XX of the General Agreement on Tariffs and Trade allows measures necessary to protect public morals or human, animal and plant life, but the WTO generally takes a strongly pro-trade approach to interpreting its rules which can minimise environmental and other considerations. The WTO in general encourages the use of international standards when member countries place trade restrictions on products for reasons such as food safety or environmental quality, and countries seeking to apply higher standards have to provide very strong scientific justification (for example in the ongoing EU-US dispute over beef treated with growth hormones).

5.3.2 In the field of Genetic Modification, this means that, for example, if the EU tried to insist that GM soya from the USA be segregated at source and refused to accept non-segregated imports, the US government would be able to take the EU before a WTO panel, and would probably win. The same outcome is quite likely even if the EU was only seeking to insist on labelling of GM imports.

5.3.3 As indicated elsewhere in this paper, however (see 3.1.2), there is still uncertainty over the impact of GM products on consumer safety and biodiversity, and the WTO fails to allocate sufficient weight to these considerations. A recent attempt was therefore made to negotiate a specific treaty on the international movement of GMOs under the aegis of the CBD (the Biosafety Protocol), but it has been held up by the USA and its allies in the 'Miami Group', thus allowing them free rein to use WTO disciplines to export their companies' products without hindrance. We believe that this is unacceptable.

5.3.4 The forthcoming 'Millennium Round' of WTO negotiations provide the opportunity to address many of the problems we have identified. We therefore call for:

- The WTO system to be amended to recognise the validity of Multilateral Environmental Agreements including the Convention on Biological Diversity
- Process and production methods to be allowed as legitimate grounds for trade measures where appropriate (see Policy Paper 12 *The Balance of Trade*)
- A requirement on WTO dispute panels to seek environmental advice in relevant cases
- Non-Governmental Organisations to be permitted to appear before panels
- Enhanced transparency and openness in dispute procedures
- The conclusion of a strong Biosafety Protocol to govern international movements of GMOs, including issues of liability, segregation, and conflict with other Multilateral Agreements.

## 5.4 EU Regulation

5.4.1 At the European level, Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms provides the current legislative framework whereby GM crops can be approved for cultivation on a Community-wide basis. Our key recommendation (see 2.5.3 above) is to seek an EU-wide moratorium on commercial growing. However, under the existing rules, we believe that individual member states should be allowed to opt out of growing crops approved at the EU level. This position recognises both the principle of subsidiarity and the real differences in both environmental conditions and the climate of opinion across member states. The recent House of Lords Select Committee Report also backed this approach. The current controversy over the refusal of Austria, Luxembourg and France to allow the cultivation of a GM maize approved by the Commission in 1996 shows that a rigid Community-wide approach is problematic.

# Genetic Medical Treatments

6.0.1 Recombinant DNA technology is now routine and commonplace throughout biological and biomedical research. This technology has led to a vast increase in our knowledge of disease processes and the prospects for therapies and is essential to research in areas as widely different as the understanding of brain function, inheritance of genetic disorders, and the fundamental basis of cancer.

6.0.2 There are already many practical applications of the new genetic technology. They include: prenatal diagnosis of genetic disorders; rapid diagnosis of infections such as hepatitis; synthesis of therapeutic agents such as insulin and blood clotting factors; tracing the routes of infections from the genetic fingerprints of disease-causing organisms; and analysing types of cancer so that the most appropriate treatment can be given.

6.0.3 There has been less concern about medical applications of genetic modification than agricultural ones, because medical applications generally involve contained use. However there are several issues of public concern arising from this rapidly advancing technology. They are principally in the areas of cloning, gene therapy, xenotransplantation and the use/abuse of knowledge about the genetic make-up of individuals.

## 6.1. Human Cloning

6.1.1 Cloning is any procedure that creates genetically identical cells or individuals. Farm animals have been cloned for some time simply by splitting early embryos to mimic natural twinning. (Plant cuttings are also 'clones' - in fact, the word ‘clone’ comes from the Greek word for a twig.)

6.1.2 The cloning of the sheep Dolly (1997) and Polly (1998), however, represents a new technology. In this cloning

method, an embryo is created, not from fusion of egg and sperm cells, but from an egg cell into which a nucleus is artificially transplanted. In the case of Dolly, the donor nucleus was from a fully developed udder cell.

6.1.3 Although the purpose behind the creation of Dolly was to produce blood clotting factor IX, the reason for the general public concern following Dolly’s creation was that the new technique presents real new possibilities for human cloning.

6.1.4 Though currently illegal in the UK and elsewhere, there may well be pressure in the future to allow human reproductive cloning. As the technology becomes more familiar, there will be those who will say that human reproductive cloning should be an option for fertility treatment. It has recently been suggested that human embryos could be twinned and one frozen as a possible replacement if the first child dies.

6.1.5 We consider that the objections to human reproductive cloning are overwhelming. We therefore advocate:

- The continuation of the existing ban on human reproductive cloning

6.1.6 However, cloning does not have to result in a fully developed adult individual. Cloned embryos could be produced for research purposes and never allowed to develop beyond a certain stage. Current regulations, in any case, allow the use of

embryos up to 14 days old to be used for research purposes and under strict licence.

6.1.7 Similarly, a cloned embryo could be produced in the laboratory as a donor of cells for organ or tissue culture and never allowed to develop beyond a few cells. This technique might be used, for example, to produce human skin tissues for grafts, or to find ways of generating replacement organs for transplantation.

6.1.8 While some have ethical objections to this form of human cloning, we believe such objections are outweighed by the potentially very great benefits. We therefore support the use of cloned embryonic stem cells for research and therapeutic purposes.

6.1.9 There are two current regulatory bodies relevant to human genetics. The Human Fertilisation and Embryology and Authority (HFEA) is the statutory body that regulates embryo and fertility research. Its function is the licensing of fertility treatments, embryo research and storage of eggs and embryos. It was established by the Human Fertilisation and Embryology Act, 1990, and keeps under review the whole area of fertility treatment and research. The Human Genetics Advisory Commission (HGAC) was set up in 1996 to keep scientific progress under review, to report on issues arising from new developments in human genetics and to advise on ways to build public confidence.

6.1.10 Both of these bodies command general confidence, and we presently have no recommendations to change them. The Government has recently proposed merging the HGAC, the Advisory Committee on Genetic Testing (ACGT) and the Advisory Group on Scientific Advances in Genetics (AGSAG) into a new strategic advisory Commission called the Human Genetics Commission (HGC). The remit of the new Commission will be to advise on applications of biotechnology in healthcare, and the impact of human genetics on people's lives. How the HGC will work in practice remains to be seen.

## 6.2 Gene Therapy

6.2.1 Somatic gene therapy is the use of genetic material (DNA) to treat genetic disorders or cancer - by introducing specific pieces of genetic material into cells. The DNA can be viewed as a drug, administered to treat or ameliorate a disease. (For example it may be possible to kill cancer cells selectively by treating them with a chemical that kills them only if they express a certain gene - the gene is introduced into them in such a way that it will only be expressed in cancer cells, so only cancerous tissue will be killed).

6.2.2 The risks involved in this are probably few but could include unexpected effects of the introduced DNA - either if it has unexpected properties or if it disrupts existing genes.

6.2.3 Approval for somatic gene therapy or gene transfer research on human subjects must be obtained from the Gene Therapy Advisory Committee, a non-statutory advisory body reporting to the Secretary of State for Health. It has 17 members, a majority of whom at present are scientists.

6.2.4 We support the continued development of somatic gene therapy.

6.2.5 So-called 'germ-line gene therapy' is currently illegal. This would involve genetic modification applied to embryos to correct genetic defects at a very early stage in development.

6.2.6 It is already possible to inspect embryos produced by in vitro fertilisation and to select particular ones for implantation. This is sometimes already done for medical reasons - for example, female embryos may be selected to avoid the birth of a child with haemophilia (a sex-linked genetic disorder in which the affected person has blood which does not

clot easily). Embryos can also be analysed for an increasing number of genetic disorders. This kind of information can be obtained by removing a single cell from an 8-cell embryo. The embryo develops normally in spite of losing a cell, so all the embryos from an in vitro fertilisation can be tested and only 'healthy' embryos implanted.

6.2.7 Germ line intervention would take this one stage further, by genetically modifying faulty embryos. We consider such procedures to be unacceptable for two reasons.

6.2.8 First, the risks involved are too high to allow the procedure to be tried. The genetic manipulation may have unintentional effects and affect development of the individual. The result of the manipulation could later be inherited by the offspring of the individual concerned, and so any adverse effects could be propagated to numerous people.

6.2.9 Secondly, there is also concern that this technology, if developed, could be used for eugenic purposes. It could, eventually, be possible to select embryos for non-medical reasons - intelligence, height, eye colour for example. This might be done to suit the individual preferences of parents, or in an attempt to 'improve' the human race. We completely reject the notion of selective breeding of humans.

6.2.10 We therefore recommend:

- Germ line genetic manipulation of humans should remain illegal

## 6.3 Xenotransplantation

6.3.1 Xenotransplantation is the transplantation of living tissue, including whole organs such as hearts and kidneys, between different animal species and from animals into humans. Current medical research is focusing on the pig as the source of organs for donation to humans. Source animals are genetically modified in order to reduce the chances of the transplanted organ being rejected by the host. Development of these procedures is regulated by the UK Xenotransplanation Interim Regulatory Authority (UKXIRA).

6.3.2 There is a chronic shortage of donor organs, and xenotransplantation is one possible solution to this problem (for an alternative approach, see 6.1.7). However, it plainly raises a number of safety and animal welfare questions. Some also express ethical concerns.

6.3.3 Xenotransplantation raises particular problems of animal welfare, because donor animals have to be kept in sterile conditions and separated from other animals. Our general approach to animal welfare is set out in the next chapter.

6.3.4 The most serious objection to xenotransplantation is on grounds of potential danger to human health. There are concerns that so-called endogenous retroviruses which are present in the DNA of the donor animal and which are harmless to that animal may be activated in the human recipient, and give rise to new human diseases. The risks are forecast to be small because the virus would have to be 'expressed' in the human host when it is not in the animal and the expression would have to be disease causing. The problem is that although predicted risks are small, they are unknown.

6.3.5 Work is underway to try to quantify the risks based on testing all those recipients of earlier attempts at animal tissue transplants or support (for example diabetics who have had pig pancreas cells, and liver patients who have had temporary liver bypass though an animal liver) to see if they have any evidence of the viruses. Even when this research is complete, because previous experience is limited and the numbers studied small, the degree of certainty of safety will be limited. In the light of current scientific and medical knowledge, we believe the risks are too

great to undertake human trials at this stage. Accordingly:

- There should be no human xenotransplantation trials at present

6.3.6 Even if after the assessment of risks, they were felt to be sufficiently small to allow human trials, the technique is so novel, and the potential implications of a transmittable, pathogenic, expressed virus are so great, it would be necessary to ensure that all participants in trials are subject to extensive testing and surveillance. It is not yet clear how participants can be forced to accept indefinite health surveillance without legislation and there are significant civil liberties issues at stake. We therefore further recommend:

- There should be no human trials commenced until the issue of adequate surveillance has been addressed, by legislation if necessary

## 6.4 Confidentiality, Counselling, Insurance

6.4.1 The growth of knowledge about the human genome makes it much easier to predict on the basis of DNA tests which individuals are likely to suffer from a variety of serious medical conditions. This raises two key issues

6.4.2 Firstly, individuals will have advance warning of conditions they may be likely or certain to develop at some point in the future. Many will need counselling to help them cope with the mental and emotional stress, and some may wish to be protected from this information. At the same time, there may be pressure on known carriers of certain genes (for example the gene for Huntington's Chorea) to inform an intending spouse or their children.

6.4.3 Secondly, there arises the possibility of a genetic 'underclass'. People with genetic defects may find it impossible to obtain medical, life or mortgage insurance, and may find themselves subject to discrimination in employment, if the practice of genetic screening becomes commonplace.

6.4.4 We recommend that:

- The confidentiality of an individual's genetic medical records should remain absolute - insurance companies, employers and others should not be entitled to require genetic testing

- Information about genetic defects should only be passed on to relatives with the consent of the original patient

- Counselling should be available to all who need it

# Transgenic Animals and Animal Welfare

7.0.1 The key challenge in formulating policy on transgenic animals is how to reconcile the substantial human benefits which can be achieved with animal welfare and ethical considerations.

## 7.1 Transgenic Animals

7.1.1 Transgenic animals have had their genetic make-up altered, usually by inserting, altering or removing a gene from an embryo in the laboratory before implanting the embryo into a surrogate mother's uterus.

7.1.2 Transgenic animals are extremely useful in medical research. The animal most commonly used for this purpose is the mouse. Use of transgenic mice allows the creation of animal models for human genetic disorders and makes it possible to study these diseases, their development and possible treatments in the laboratory.

7.1.3 Transgenic animals can also be created to produce therapeutic products. Sheep producing therapeutic proteins in their milk, such as blood clotting factors used to treat haemophilia, have already been created. The use of transgenic animals offers the possibility of cheap, safe products for human therapy and has several advantages over other sources of these proteins. For example, proteins derived from human sources can be contaminated with human viruses or prions (as happened in the case of human growth factor preparations used in the 70s and 80s which were contaminated with the causative agent of Creutzfeldt Jacob disease); and proteins from unmodified animals or from GM micro-organisms are not exactly the same as the human protein, so may cause side-effects.

7.1.4 The third major use of transgenic animals is in agriculture, where new varieties of domestic animal can be developed with advantages in terms of yield, disease resistance and other characteristics.

## 7.2 Genetic Modification and Animal Welfare

7.2.1 All of these uses of animals raise animal welfare issues. In considering how acceptable genetic modification techniques are in animal welfare terms, we accept the principles laid down in the last comprehensive Liberal Democrat statement on animal protection, Federal Green Paper 27 *A Matter of Conscience*, with regard to the justification of animal experiments: they should only be permitted when the suffering is minimised and the benefit can be weighed favourably against the suffering caused. This means that there has to be a calculation of the benefits against any suffering for each individual project. The existence of valid alternative methods which do not involve animal suffering will be an important consideration.

7.2.2 However, this principle does imply that whereas significant animal suffering may be justified where absolutely necessary for research which might save human lives, animal suffering is unlikely to be justified for non-essential purposes, such as increasing agricultural yields. In particular, we do not believe that the genetic modification of animals to facilitate intensive farming methods can be justified. Accordingly:

- Genetic modification of animals to facilitate intensive farming methods should be prohibited

7.2.3 This raises the question of how this balance is to be struck. There are a number of existing regulatory bodies which are in various ways involved in supervising the creation of transgenic animals and the use of animals in biotechnology generally, including the Animal Procedures Committee (APC), the UK Xenotransplantation Interim Authority (UKXIRA), and the Farm Animal Welfare Council (FAWC). However, the rapid development of this technology means that gaps may easily open up in the regulatory framework; for example, were cloned animals to become available for use in commercial agriculture, it is not clear who would be responsible for assessing the long-term effects on their welfare. It is also to some extent the case that these bodies supervise biotechnology more from the standpoint of human safety than animal welfare.

7.2.4 *A Matter of Conscience* calls for the creation of an Animal Protection Commission to co-ordinate and upgrade the animal protection role of all government departments. We recommend that this Commission also be given the specific task of advising the regulatory bodies named above on the animal welfare implications of genetic modification, and ensuring that arrangements for animal welfare supervision keep pace with developments in the field. The Animal Protection Commission should also have a role in deciding the balance of human benefit against animal suffering.

7.2.5 We also recommend:

- The establishment of a stakeholders' forum, including representatives from farming, the medical profession and animal welfare organisations, to promote an informed public debate on these questions

- The impact of the use of transgenic animals in agriculture on the biodiversity of domesticated species must be closely monitored.

# Glossary

**ACRE:** Advisory Committee on Releases into the Environment

**ACNFP:** Advisory Committee on Novel Foods and Processes

**ACGM:** Advisory Committee on Genetic Modification

**DETR:** Department of the Environment, Transport and the Regions

**DNA:** Deoyribonucleic Acid, the molecule which contains all genetic information in the cell for cellular structure, organisation and function.

**Expression:** Manifestation of the genetic material of an organism

**Gene:** A small segment of DNA which holds the information needed to make one protein.

**Genome:** The sum total of all the genes of an organism

**Germ line:** Present in the DNA of an individual so that it affects their offspring

**GMO:** Genetically Modified Organism; any living thing which has been genetically modified.

**Intellectual Property Rights:** The legal rights of inventors over their inventions.

**Marker:** A genetic modification of an organism so that it produces a substance not occuring naturally by which its presence can then be traced.

**Pathogenic:** Capable of causing disease.

**Recombinant DNA:** DNA that has been recombined using constituents from different sources.

**Somatic gene therapy:** genetic treatment which affects the individual concerned, but cannot be passed on to their offspring (see germ line, above).

**Transgenic:** Containing genes of another species.

**WTO:** World Trade Organisation.

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