GENETIC TECHNOLOGIES:
A Review of Developments in 2001

GeneWatch UK

Briefing Number 17
February 2002

During 2001, the commercialisation of GM crops and foods has remained stalled in Europe and disputes about their future have continued elsewhere in the world. The agricultural biotechnology industry has separated from the pharmaceutical industry and its future looks increasingly uncertain. In the field of human genetics, cloning, the use of human embryos and genetic testing have remained the focus of debate. Questions are now being raised about whether the emphasis on genetics in human medicine will increase inequalities in access to health care and detract from addressing the social and environmental factors that are usually more important in disease.

This briefing reviews the major developments in the science, regulation and politics of genetic technologies in 2001 and considers their implications.

GM Crops and Foods

In 2001, the *de facto* moratorium on new approvals of GM crops and foods in Europe continued and there have now been no new approvals since 1998. A new European Directive on the Deliberate Release of Genetically Modified Organisms (2001/18/EC) was agreed in 2001 and has to be implemented by Member States by October 2002. The Commission wanted to evaluate GM crops according to the new Directive before it had been implemented as a way of allowing commercialisation to proceed. However, Member States rejected this move because they wish to see complementary regulations covering the labelling and traceability of GM food put in place before further commercialisation is allowed.

In the rest of the world during 2001, commercial growing remained largely restricted to the USA, Argentina, Canada and China, which together grew 99% of the 52.6 million hectares of GM crops worldwide – a 19% increase on 2000 (see Table 1). Of these four countries, the USA dominates, growing nearly 70% of the total with Monsanto's *Roundup Ready* soybean making up 63% of all GM crops grown (see Table 2). Insect tolerant (*Bt*) cotton and maize were the other main GM crops grown. China increased its area of *Bt* cotton in 2001 but no new GM food crops have been approved for cultivation because of concerns over trade. A total of 13 countries grew GM crops commercially, one less than in 2000.

Whilst much is made of the increasing area of GM crops being grown, more striking is the lack of any new traits. Herbicide tolerance, insect resistance and combinations of the two traits remain the only GM options for farmers. This reflects a lack of innovation and stagnation in the agbiotech industry following reduced investment in R&D as a result of the industry's failing fortunes[1].

Table 1: Commercial cultivation of GM crops worldwide (in millionsof hectares)[2]

COUNTRY	1998	1999	2000	2001
USA	20.5	28.7	30.3	35.7
Argentina	4.3	6.7	10.0	11.8
Canada	2.8	4.0	3.0	3.2
China	<0.1	0.3	0.5	1.5
Australia	0.1	0.1	0.15	0.21
South Africa	<0.1	0.1	0.2	0.27
Mexico	<0.1	<0.1	<0.1	<0.1
Spain	<0.1	<0.1	<0.1	<0.1
France	<0.1	<0.1	<0.1	0.0
Germany	0.0	<0.1	<0.1	>0.1
Indonesia	0.0	0.0	0.0	>0.1
Portugal	0.0	<0.1	<0.1	0.0
Rumania	0.0	<0.1	<0.1	>0.1
Bulgaria	0.0	0.0	<0.1	>0.1
Uruguay	0.0	0.0	<0.1	>0.1
Ukraine	0.0	<0.1	0.0	0.0
TOTALS	**27.8**	**39.9**	**44.2**	**52.6**

Table 2: Commercial cultivation of GM crops worldwide by trait
(%of total GM crops grown)[2]

	HERBICIDE TOLERANT	Bt INSECT RESISTANT	BOTH TRAITS	Total % by Crop
Soybean	63%			63%
Oilseed Rape	5%			5%
Maize	<5%	11%	<5%	19%
Cotton	<5%	4%	<5%	13%
Total % of GM Crops by Trait	77% (40.6 million hectares)	15% (7.8 million hectares)	8% (4.2 million hectares)	

GM crop trials in the UK

As in 2000, over 95% of UK crop trials involved herbicide tolerance, reflecting the wider stagnation of the technology

There were 153 GM crop trial sites in the UK in 2001 (158 in 2000). 105 of these (69%) involved farm-scale trials to evaluate the impact on biodiversity of GM herbicide tolerant oilseed rape, maize, sugar and fodder beet. The sugar beet from one of the farm-scale trials is also being fed to cattle to determine whether the DNA can be found in milk. Of the remaining sites, 14 were for National Seed Listing trials; 17 were directed at safety questions; and 17 were for research and development. 9 of the 'safety' trials were the 'BRIGHT' trials looking at the agricultural and safety aspects of herbicide tolerant GM crops (see GeneWatch Briefing No 8). The other safety trials were intended to assess environmental and agricultural impacts (6); food safety (1); and 'unpredictable' effects (1). All of the safety trials were publicly funded although commercial R&D and other trials often include safety elements such as gene flow and the farm-scale trials address some aspects of environmental safety. As in 2000, the vast majority (over 95%) of the trials involved herbicide tolerance, reflecting the wider stagnation of the technology.

R&D trials included herbicide tolerant sugar beet (3 sites – all *Roundup Ready* from Monsanto and Syngenta) and oilseed rape (8 sites – *Liberty Link* from Aventis); oilseed rape with an inducible promoter where a chemical (alcohol) is used to activate a gene (1 site – Syngenta); potatoes with altered carbohydrate (1 site – Advanced Technologies Cambridge – a subsidiary of British American Tobacco) and disease resistance (3 sites – Syngenta and Advanced Technologies Cambridge); and herbicide tolerant barley with improved baking qualities (1 site – John Innes Institute).

A further 30 farm-scale trial sites with herbicide tolerant oilseed rape were planted in the autumn of 2001 but will not be harvested until 2002. The same applies to 6 National Seed Listing trials and 7 R&D trials with the same GM crop.

UK farm-scale trials – continuing conflict

More than 30 of the 105 farm-scale trial sites were opposed by local communities, organic farmers and national organisations

During 2001, the farm-scale trials (see GeneWatch Briefing No 8 for background information) continued to be a focus of conflict over the future of GM crops. According to the current agreement between industry and Government, the decision about commercialisation is dependent upon their outcome despite other outstanding issues. More than 30 of the 105 farm-scale trial sites were opposed by local communities, organic farmers and national organisations, and around 21 were damaged by activists[3,4]. In November 2001,

a jury did not convict two activists who had destroyed a trial site in 2000, accepting their defence that they acted to prevent greater harm arising in the future[5].

One of the trial sites was withdrawn just before it was to be planted with GM maize. The proposed site at Wolston in Warwickshire was just under two miles from Ryton Organic Gardens, a research centre run by the Henry Doubleday Research Association (HDRA), the country's leading organic research organisation. They had not been consulted about the site and a vigorous local campaign led to the Government supporting the withdrawal of the site, especially because the RSPB had threatened to resign from the Scientific Steering Committee if it went ahead[6].

There have also been strong protests at farm-scale trial sites in Wales and Scotland. In Wales, a farmer at Mathry in Pembrokshire decided not to go ahead with a GM maize trial because of local concerns about the impact on other farmers[7]. Since then, the Welsh Assembly has called for a moratorium on GM crop trials in Wales and called for the European Commission to implement increased separation distances.

In Scotland, a farm-sale trial with autumn sown oilseed rape at Munlochy in Ross-shire has also met with considerable local opposition. A vigil has been established on council land close to the farm and, in an extraordinary display of solidarity with their electorate, the Highland Council has given planning permission for two caravans, a yurt and toilet to remain in situ until the end of the GM crop trial next summer[8].

Public opinion and the demand for public participation in decision making

The issues raised in local protests about GM crop trials have attracted sympathy among the wider public

Public concern about GM foods remained high during 2001 and research showed that the issues raised in local protests about GM crop trials have attracted sympathy among the wider public. Opinion poll data continued to reflect the public's demand for choice and more information. Other research shows that the public wish to participate directly in decisions about GM crops and foods and that failure to enable this fuels conflict and controversy.

A National Consumer Council opinion poll in August 2001 showed clear consumer support in the UK for the 'right to know' whether food is produced from GM crops or from animals fed with GM feed. Almost two-thirds (64%) thought it was important that food containing GM ingredients is labelled and over three-quarters (79%) thought that meat and other products from animals fed with GM feed should be labelled[9].

A Eurobarometer survey of all European Union Member States conducted in May-June 2001 showed that the desire to have information about GM foods was widely shared across Europe (see Table 3). Almost 95% wanted to have the right to choose or reject GM foods and 70% did not want GM food at all.

Qualitative research which considered genetically modified organisms (GMOs) as part of a study on public participation showed that in the six countries included (Denmark, France, Germany, Portugal, the Netherlands, and the United Kingdom) there is a clear public desire to participate in the assessment of genetic modification. In part, this demand was thought to stem from a growing distrust of government institutions and science[11].

Table 3: Eurobarometer results: Participants were asked the following question: Would you say that you are more inclined to agree or disagree with each of the following propositions on genetically modified foods?[10]

	Inclined to agree (%)	Inclined not to agree (%)	Don't know (%)
I want to have the right to choose	94.6	2.5	2.8
I want to know more about this kind of food before eating it	85.9	9.3	4.8
They should only be introduced if it is scientifically proven that they are harmless	85.8	8.0	6.1
I do not want this type of food	70.9	16.9	12.2
They could have negative effects on the environment	59.4	11.9	28.7
The dangers have been exaggerated by the media	33.1	44.3	22.6
This kind of food does not present any particular danger	14.6	54.8	30.6

In their report on the farm-scale trials, the Government's Agriculture and Environment Biotechnology Commission (AEBC) recognised that a lack of public involvement in deciding where the trials were sited had fueled the controversy[12]. In addition, a lack of opportunities to debate the wider issues about GM crops and foods made the trials the focus of wider dissent than the questions they were intended to address. The AEBC's recommendations emphasised the need for public consultation and for socio-economic concerns to be addressed when deciding whether and under what conditions commercialisation of GM crops should be allowed. In particular, the co-existence of organic and non-GM crops with GM crops was identified as a question which had to be addressed because the contamination issue had become acute.

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Is there a future for GM crops and foods in the UK?

It is becoming clear that the farm-scale trials with GM crops cannot provide a basis for decisions about commercialisation in the UK. When the trials end in the summer of 2003, any decision to proceed will meet hostility if the Government does not give weight to the broader concerns and recognise that scientific uncertainties will remain about the impacts of growing GM crops.

Four conditions are emerging as essential prerequisites if GM crops and foods are to have any future in the UK:

- legislation must be in place to establish who would be liable for any harm to the environment and to other non-GM farmers and beekeepers;
- consumer choice must be maintained by establishing mechanisms to trace the growing and use of GM crops (traceability) and labelling based on the means of production must be introduced;
- rules must be in place to ensure that contamination from GM crops does not compromise organic and non-GM growers;
- the recommendations of the AEBC about the farm-scale trials must be followed. These include the need for consultation on the acceptability of the remaining sites, a review of other necessary data (such as the performance of GM crops elsewhere) and whether there are significant

gaps in knowledge about other potential impacts, together with a public debate about the acceptability of GM crops before commercialisation is allowed.

Will the Government meet these conditions and take steps to control developments in the public interest or simply leave interested parties to argue amongst themselves?

Liability provisions were excluded from the new Deliberate Release Directive (18/2001/EC) because it was decided that rules covering *all* potentially environmentally damaging activities (including chemicals, for example) would be a better way to proceed. However, the draft document on liability produced by the European Commission in the autumn of 2001 restricts the scope of harm to certain specially designated areas (known as 'Natura 2000' sites) and some threatened bird species. Not only is there no provision for damage to the agricultural environment and areas outside the Natura 2000 sites, but economic damage to neighbouring farmers as a result of contamination is not included. Most observers consider that it will take many years for any European liability rules to be agreed – long after GM crops may be grown commercially in Europe. The UK Government could introduce national legislation to cover all areas of potential harm – environmental, human and socio-economic. Failure to do so before even considering allowing GM crops to be grown commerically will cast doubt on it's impartiality.

The FSA has ignored public attitudes and appears to have been swayed by the economic interests of the food producers

With regard to GM food labelling, whilst the Food Standards Agency (FSA) purports to place the interest of consumers uppermost, it wants to restrict consumer choice over GM foods. Its statement on GM food labelling says that: *"The Food Standards Agency supports consumer choice and recognises that some people will wish to choose not to buy or eat GM foods however carefully they have been assessed for safety"* [13]. However, the opinion of the FSA Board[14] is that labelling of GM foods should not be extended to include the means of production (as the European Commission is proposing) but should be restricted to when foreign DNA or protein is present in the final product. The FSA Board also supported a new GM-free label, but this simply reflects the FSA's view that only '*some people'* want to avoid GM food completely and that a niche market of more expensive GM-free food will meet their needs. In coming to this opinion, the FSA has ignored the available information on public attitudes (see above) and appears to have been swayed by the economic interests of the food producers who have lobbied against comprehensive labelling of GM foods based on the means of production. The Government does not have to follow the opinion of the FSA in its discussions on the proposed new labelling laws and how it proceeds will be a real test of its commitment to consumer choice. However, early indications are not encouraging.

As far as protecting organic and non-GM farmers from contamination by GM pollen is concerned, the only safeguards are a set of voluntary guidelines established by the pro-GM industry body SCIMAC (Supply Chain Initiative on Modified Agricultural Crops) and the conditions imposed by the Government's licences allowing the trials to take place. These specify the required separation distances between GM and non-GM crops and practical measures such as the cleaning of equipment after harvesting and sowing. However, not only is it emerging that the recommended separation distances will not prevent cross-pollination causing more than 1% contamination in non-GM food (currently proposed as 'acceptable' before labelling is required), levels in seed will have to be considerably below this because further contamination may occur during

Recommended separation distances will not prevent cross-pollination causing contamination in non-GM food

growing, transport and processing. When giving its opinion in March 2001, the European Commission's Scientific Committee on Plants said that separation distances would have to double to 3,000 metres to maintain sugar beet seed contamination levels below 0.3%. For oilseed rape, the Committee was unable to give an opinion because new data on contamination of hybrid varieties suggested that levels of cross-pollination were higher than had been anticipated and that doubling current separation distances would not be sufficient[15]. This poses considerable problems for the future of non-GM seed production and will demand strict control on where GM crops are grown. There is little evidence that the Government is making progress in this area.

The Government has accepted the need for wider issues to be taken into account in the decision-making process about commercialisation

Early in January 2002, the Government responded to the AEBC's report and recommendations[16]. In a welcome response, they have accepted the need for wider issues to be taken into account in the decision-making process about commercialisation. However, plans for local consultation remain constrained by the regulatory framework.

GM animal feed rejected

In January 2001, Tesco announced that their own-brand meat products will be produced only from farm animals fed with non-GM feed and committed itself to non-GM dairy products. Asda has announced plans to ensure its chicken, pork and eggs come from animals reared on GM-free feed. Marks & Spencers also announced in January that their fresh beef, lamb, chicken, eggs and salmon would not come from animals fed GM food.

Demand for non-GM animal feed has spread to the rest of Europe and now accounts for an estimated 20-25% of imports[17] . Carrefour/Belgium, Wiesen-hof/Germany, and McDonald's/Europe (for its chicken) are among those intending to sell or use only products from animals fed with non-GM feed. Most non-GM soya for use in animal feed comes from Brazil.

Genetics and Human Health

Evidence continued to mount that patents on human genes were stifling research and making new biotech treatments prohibitively expensive

In 2001, the majority of health-sector biotech companies in the world remained loss-making enterprises. However, much hype continued to surround the discovery of new genes 'for' various diseases and the promise of a new genetic revolution in healthcare.

February 2001 saw the publication of the first draft of the human genome following the biggest international collaboration ever undertaken in biology. The International Human Genome Sequencing Consortium found evidence for the existence of 29,691 human genes[18] and the commercial genome project of Celera Genomics found 39,114 genes[19]. This provoked some searching questions about whether so few genes (only around twice as many as a simple worm or fly) could really be the essence of a human being as some scientists had claimed[20]. Some revised estimates have now doubled to between 65,000 and 75,000 genes[21] although this is still far fewer than had been expected.

Patenting of human genes

In 2001, evidence continued to mount that patents on human genes were stifling research and making new biotech treatments prohibitively expensive[22,23].

"*The intellectual property arena is nothing less than a minefield…if a gene sequence is patented, you can't necessarily design around it. What type of discovery associated with the gene sequence would entitle somebody to lock up a whole area of research and prevent competition?*"

Dr Elliot Sigal, Senior Vice President of Early Discovery and Applied Technology, Bristol-Myers Squibb's Pharmaceutical Research Institute[24].

A patent allows the holder to exclude anyone else from making, using or selling an invention for up to 20 years. Since 1980, patents have also been granted for living organisms and gene sequences. The patenting system therefore allows biotechnology companies to claim human genes and proteins as well as new products and production methods as part of their 'intellectual property' portfolios. However, genes exist in nature and many people object to commercial companies claiming to have invented them and seeking to own them.

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Even so, in January 2001, US district court judge William Young issued a lengthy judgement in favour of the world's leading biotech company, Amgen, in its patent dispute with Transkaryotic Therapies (TKT) and Aventis over its Epogen drug for kidney dialysis patients. Amgen won the race to patent the erythropoietin (EPO) gene in the mid-1980s[25] (following two decades of US Government funded research) and hence a monopoly on its production (under the trade name Epogen). Amgen claimed that TKT and Aventis had infringed its patents by developing a completely different approach to activate the EPO gene and produce EPO. Although EPO occurs naturally in the human body, Judge Young ruled that Amgen's patents were infringed by anyone making the same product - no matter what process was used. TKT is appealing against this judgement but its prospects are thought to be slim. Such monopolies make new biotech treatments prohibitively expensive - Epogen currently costs around $7,000 per patient per year[26]. Amgen's overlapping series of patents are now likely to extend its monopoly on EPO for nearly 30 years.

In another important patent dispute, Myriad's European patent for the BRCA1 gene, which is associated with an increased risk of breast cancer, is being challenged by the Institut Curie, France's leading cancer centre[27]. The French Ministry of Health claims that the patent gives Myriad an excessive monopoly and threatens basic research. The Ministry claims that Myriad's BRCA1 test costs $2,500 and fails to identify 10-20% of mutations compared with $680 for a test developed in France. French scientists also warned that patenting human genes meant that the same problems could arise with other genetic tests in future. The appeal procedure is expected to last for several years.

Despite the implications of gene patenting, the number of patent claims on human genes and proteins continued to spiral in 2001

Despite the implications of gene patenting, the number of patent claims on human genes and proteins continued to spiral in 2001. In one example, Oxford Glycosciences - set up as a spin-off company from Oxford University in 1988 to pioneer new drug development - announced it had filed patents for over 4,000 human proteins and genes. It claimed that this was the largest single disease-associated protein patent portfolio filed to date[28,29].

GeneWatch UK highlighted another implication of gene patenting when it revealed that the world's third largest tobacco company – Japan Tobacco – had bought exclusive rights to develop and market lung cancer vaccines from two leading US biotech companies (Cell Genesys and Corixa)[30,31]. Japan

Tobacco makes three of the world's top five cigarette brands - Camel, Mild Seven and Winston – and opposes regulations designed to reduce smoking (which causes 90% of lung cancer cases). The company now hopes to exploit the gene patenting and licensing system to profit from selling future biotech treatments for the diseases that its products cause. The lung cancer patients who have taken part in research to develop these vaccines (including some whose genes were patented) are unlikely to have been aware that the marketing rights would be sold to Japan Tobacco. A major concern is the potential for Japan Tobacco to use its research to create false hope that a cure for cancer is just around the corner – cancer vaccines are not yet marketable products and in any case will at best only slow the growth or spread of existing cancers, not prevent or cure them.

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There are no safeguards in place to prevent such licensing deals as the number of patents on gene sequences increases. The recitals (introduction) to the1998 European Directive on the legal protection of biotechnological inventions state that: *"if an invention is based on biological material from a person, then they must have had an opportunity to express free and informed consent before a patent is granted"*. However, the recitals are not legally binding and the UK Government has chosen not to implement any such consent requirement in UK law.

Genetic testing in insurance and employment

2001 saw continued controversy regarding the use of genetic test results by insurers and employers to refuse insurance cover or employment. Research showed that four out of five people in Britain believe that genetic information should not be used in setting insurance premiums[32].

The use of any genetic test to set insurance premiums could lead to a 'genetic underclass' of people who cannot buy insurance and are therefore excluded from the housing market. In future, if private healthcare increases in the UK, they may also have their access to healthcare restricted. For some people, the potential for genetic discrimination by insurers and employers could be a powerful deterrent to taking a genetic test that might help the early diagnosis and treatment of a disease[33].

There are no laws in the UK to prevent insurers, employers or others discriminating against people because of their genetic makeup

Because of the key roles of environmental, lifestyle, socio-economic and other factors in most diseases, genetic test results for common, complex diseases give a highly uncertain indication of susceptibility to future illness. Even for inherited single-gene diseases (e.g. cystic fibrosis or Huntington's disease), the age of onset and/or severity of the symptoms may vary considerably. Despite the unreliability of genetic tests, there are no laws in the UK to prevent insurers, employers or others discriminating against people because of their genetic makeup. In October 2001, the Government and the insurance industry agreed a five year freeze on the use of genetic tests by insurance companies, except for high-value policies[34,35]. However, tests for genetic susceptibility to diseases such as cancer or for single-gene inherited diseases can continue to be added to an approved list and used to determine access to high-value policies throughout the five year freeze. GeneWatch UK believes that this amounts to a back-door, step-by-step approach to expanding the use of genetic tests by the insurance industry in spite of public opposition.

Human cloning and embryonic stem cells

In November 2001, the privately-funded US biotech company Advanced Cell Technology (ACT) announced that it had cloned the first human embryo[36]. A nucleus was taken from a human skin cell, placed in an empty egg and stimulated to develop into an embryo. However, the process was not very successful and out of a total of 71 donor eggs only three embryos survived to the 4-6 cell stage and none past the 6 cell stage. Consequently, ACT's announcement has been considered politically motivated to influence the debate about the use of embryos in research in the USA by arguing that such research will lead to the ability to 'grow' organs for transplant patients.

The cloning process may cause genetic mutations which cause illness or disability in later life and be passed to future generations

The next stage of human reproductive cloning would involve implanting a cloned embryo in a woman and a massive experiment on the mother and baby would begin. This would inevitably cause enormous suffering since, when animals have been cloned, they often fail to develop properly and many die before or soon after birth. The cloning process may also cause genetic mutations which cause illness or disability in later life and be passed to future generations. The scientists at ACT who carried out the first steps in human cloning have no intention of proceeding to this next stage. Rather, they want to develop 'therapeutic cloning', growing tissues - and eventually organs - from embryonic stem cells (unspecialised cells which have not yet differentiated into any specific type of tissue) which would not be rejected following transplantation. However, growing the embryos in a womb would be much quicker and easier than growing different tissue types and the temptation for others to try to clone human babies will be great[37].

The UK took steps to introduce laws to ban human cloning in 2001. However, laws vary across the world and one maverick Italian scientist, Severino Antinori, and the US company, Clonaid, claim they will find somewhere in the world to pursue their efforts to clone humans. A global ban is clearly needed and political leadership to bring this about.

The use of embryos and cloning techniques for therapeutic cloning has generated considerable controversy on moral grounds

As well as bringing the potential to clone humans, the use of embryos and cloning techniques for therapeutic cloning has generated considerable controversy on moral grounds[38]. In the UK, the use of embryos is covered by the Human Fertilisation and Embryology Act 1990. Until recently, this allowed embryos (up to 14 days old) only to be used in research on infertility, contraception, miscarriage and congenital disorders. This law would therefore need to be modified to allow embryonic stem cells to be used for research in other areas. Extending the justification to the use of embryos for other means - and particularly the creation of embryos for therapeutic cloning - caused concern based on underlying opposition to the use of embryos but also because a life was being created for use by others. It is argued that this could lead to the commodification and commercialisation of life. Those in favour emphasise strongly the promise of new cures and treatments as the driving moral imperative and that embryonic stem cells hold much more promise than adult stem cells.

In the UK, following emotional debates in the House of Commons and House of Lords in December 2000 and January 2001, legislation has been amended to allow embryo stem cell research into disease and the repair of organs as well as allowing therapeutic cloning. The UK, along with China and privately funded research in the USA, now has the most liberal policy on embryo stem cell research as it allows embryos to be created for research use if first approved by the Human Embryology and Fertilisation Authority.

In the USA, a different outcome to the debate has emerged for federally funded research. Following considerable pressure from scientists, and contrary to his election promise to the religious right, President Bush has allowed stem cell research using cloning techniques to proceed but only with already established embryo stem cultures - no new embryos can be created or used for the purpose.

The tissues and organs that might be provided through therapeutic cloning will be the preserve of the elite in society

Even if the technical and moral difficulties are overcome, the tissues and organs that might be provided through therapeutic cloning will be the preserve of the elite in society. Eggs will have to be provided (by whom and at what cost?). *In vitro* fertilisation clinics generally pay an egg donor $3,000 to $5,000 and ACT took 71 eggs from 7 women to produce its cloned embryo. Each woman donating eggs has to be treated with drugs and undergo a serious medical procedure. Costs to treat one patient could soar above $100,000 and be greater than using the most expensive drugs[39].

However, research is beginning to show that stem cells can be isolated from adults and human bone marrow stem cells have been induced to differentiate into blood vessel cells[40] and can also yield cartilage, bone, fat, tendon, muscle[41] and kidney cells[42]. If successful, this approach would be more practically feasible, respect the moral objections to creating embryos for use by others and allow an individual's cells to be used to overcome problems of transplant rejection.

Biobank UK

Plans for a UK national biobank also progressed in 2001. Biobank UK (formerly called the UK Population Biomedical Collection) will link genetic information from blood samples to individual medical and lifestyle information and is expected to include data from 500,000 people[43]. Men and women between 45 and 60 are likely to begin to be recruited to the new £60 million genetic project (jointly funded by the Medical Research Council, Wellcome Trust and Department of Health) by their doctors towards the end of 2002.

A GeneWatch report on Biobank UK highlighted the limited legal protection for participants and the potential for the research to highlight spurious links between genes and diseases[44]. Key concerns are:

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- the lack of legislation to prevent insurers and employers from misusing genetic tests developed through the biobank research;
- the lack of legislation to control commercial interests and prevent the patenting of genes;
- legal uncertainty regarding potential access to genetic information by the Government or the police;
- the need for an independent scientific review of the proposals and public justification of the costs.

The urgent need to address these issues before research begins was emphasised when leaked papers from a Government advisory group revealed that Biobank UK may later be expanded to include almost the entire UK population[45].

Conclusions

The cultivation of GM crops remains concentrated in the USA and there is little evidence of significant extension into new countries. The European Union remains effectively closed to GM crops - a situation which is unlikely to change over the next few years. In the UK, questions about whether GM crops can co-exist alongside non-GM and organic crops have led to the possibility that cultivation is only allowed in certain zones or that the UK becomes a GM-free region.

Discrimination on the basis of genetic test data may begin and preventive healthcare may be marginalised

Medical applications of genetic technologies have always had more public sympathy than GM food or crops. However, this is not a blanket acceptance and ethical issues about cloning and the use of embryos continue to make the headlines. Whilst these are important moral issues, there are equally pressing questions to be asked about how the advent of a genetic approach to health will affect not only the effectiveness of healthcare but also human rights. As companies push genetic tests for conditions which may not be treatable or where their validity is questionable, discrimination on the basis of genetic test data may begin and preventive healthcare may be marginalised. The highly individualised, patented and costly approach of genetic medicine will prove a further drain on NHS resources and increase inequalities in access to healthcare as a result.

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Printed by East End Offset, London E3 3LT